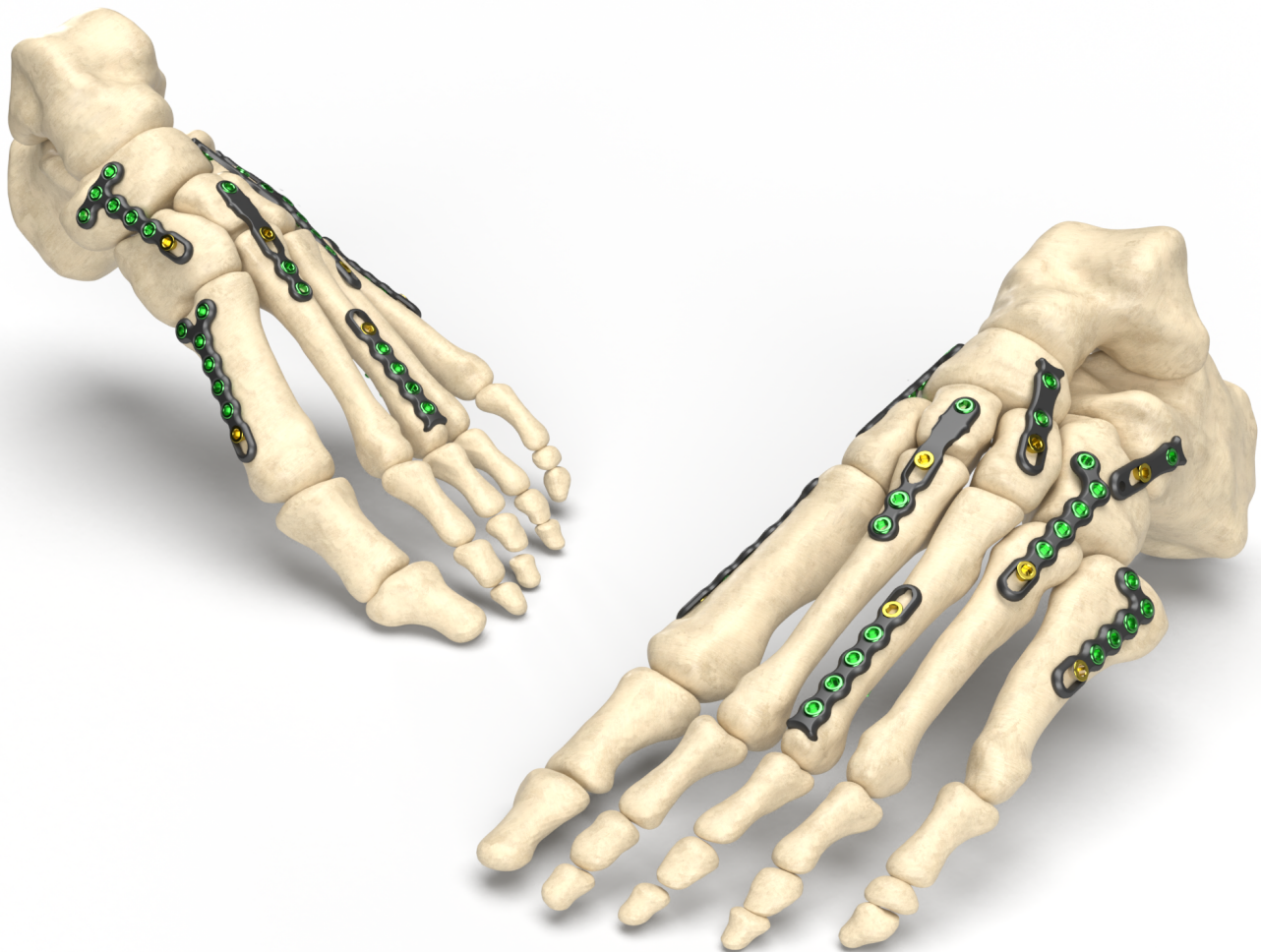


Stratum® RS

Reduced Size Foot Plating System

Surgical Technique



Stratum RS

Reduced Size Foot Plating System

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Stratum RS

Reduced Size Foot Plating System

Instructions for Use

INDICATIONS:

The Stratum RS Reduced Size Foot Plating System is intended for stabilization and fixation of small bone fragments in fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the foot and ankle, particularly in osteopenic bone.

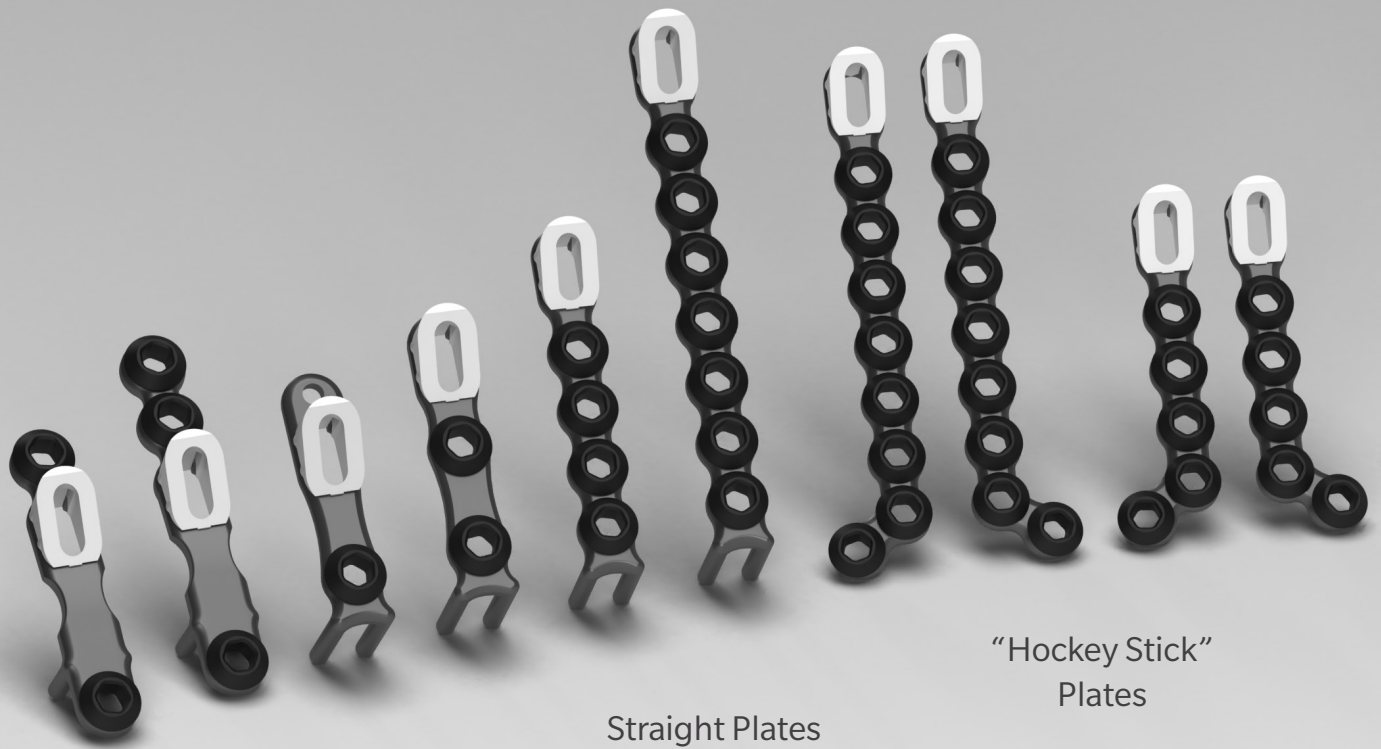
CONTRAINDICATIONS:

- Patient conditions including insufficient quantity or quality of bone and/or soft tissue.
- Blood supply limitations and previous or active infections that may inhibit healing.
- Surgical procedures other than for the indications listed.
- Patients with conditions that limit their ability or willingness to follow postoperative care instructions.
- Material sensitivity

Stratum RS

Reduced Size Foot Plating System

A Symphony for Foot and Ankle Repair[®]

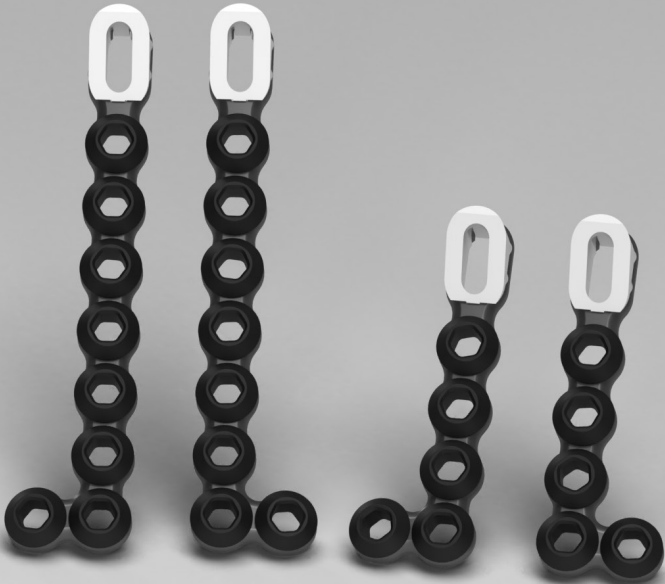


Single Lisfranc
Fusion Plates

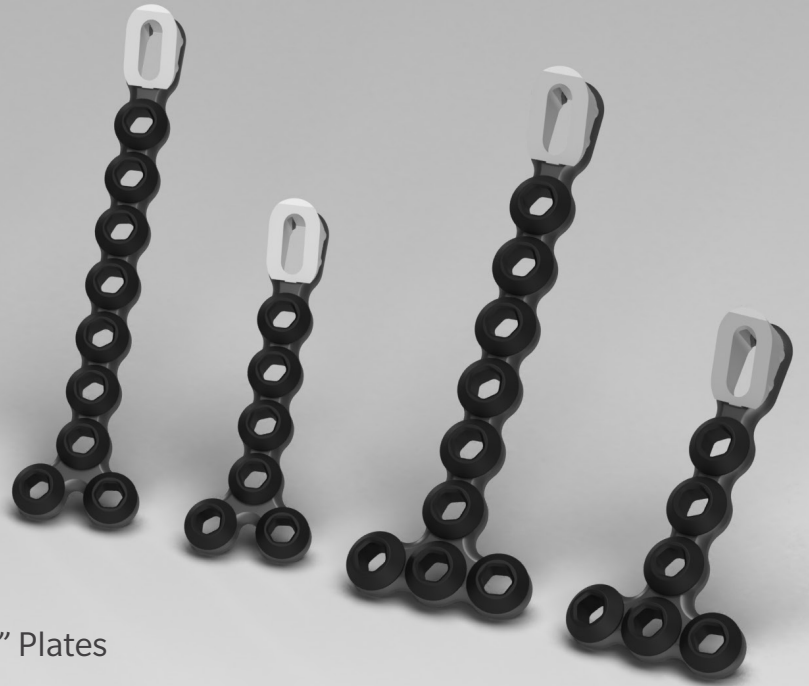
Peanut Plates

Straight Plates

"Hockey Stick"
Plates



"L" Plates



"Y" Plates

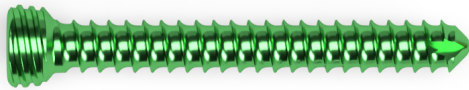
"T" Plates

Stratum RS

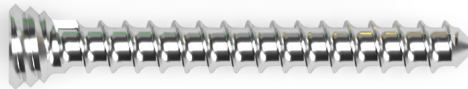
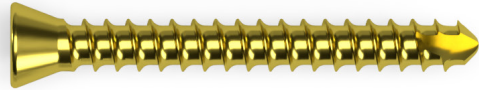
Reduced Size Foot Plating System

Screw Options

2.4mm Locking Cortical



2.4mm Non-Locking Low Profile



2.4mm Multi-Directional Locking

Sterile Screws

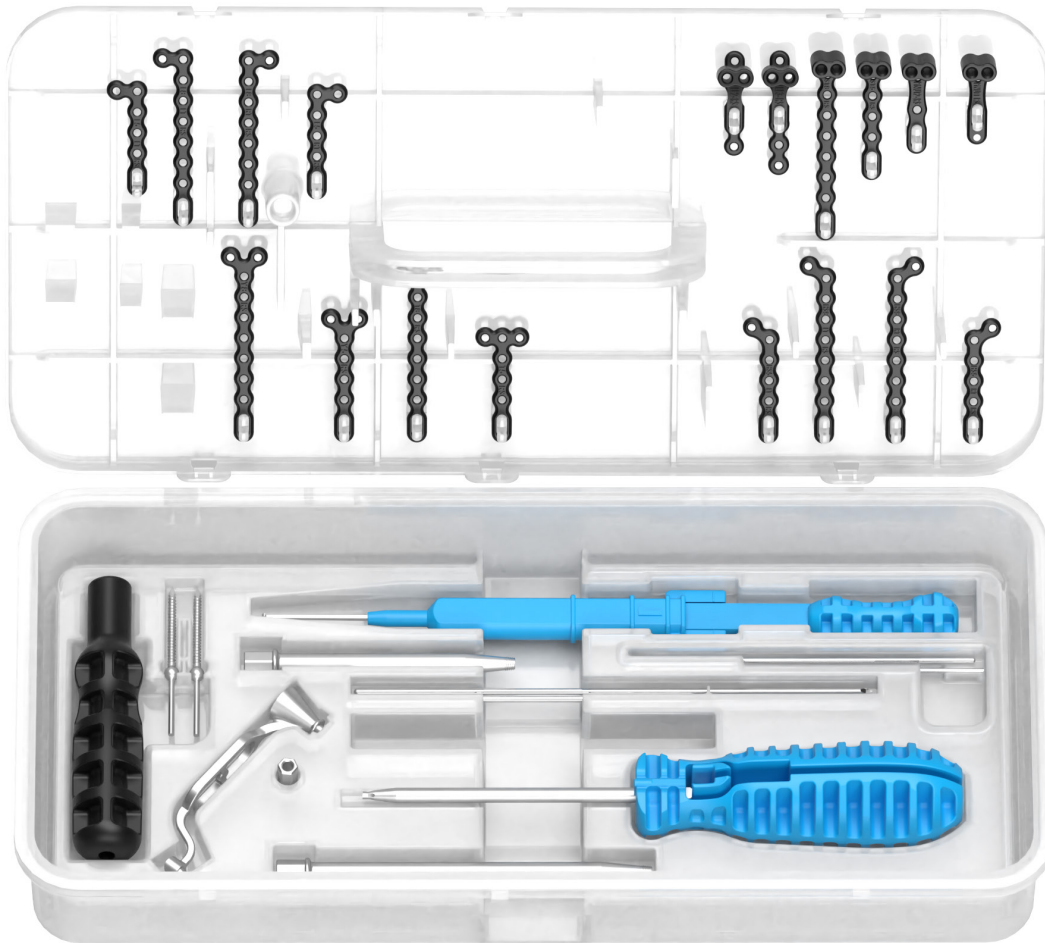
Diameter	Drill Size	Screw Type	Part No. Family	Alt Part No. Family	Length	Color
2.4mm	2.0mm	Locking - Sterile	STRM-LK-24xxRS-ST	LK24xxRSST	8-30mm	Green
2.4mm	2.0mm	Non-Locking - Sterile	STRM-NL-24xxRS-ST	NL24xxRSST	8-30mm	Gold
2.4mm	2.0mm	Multi-Directional Locking - Sterile	STRM-MDS-24xxRS-ST	MDS24xxRSST	8-30mm	Silver

NOTE: Actual screw diameter is 2.46mm.

Stratum RS

Reduced Size Foot Plating System

Sterile Disposable Kits



Reduced Size
Standard Instrument Kit

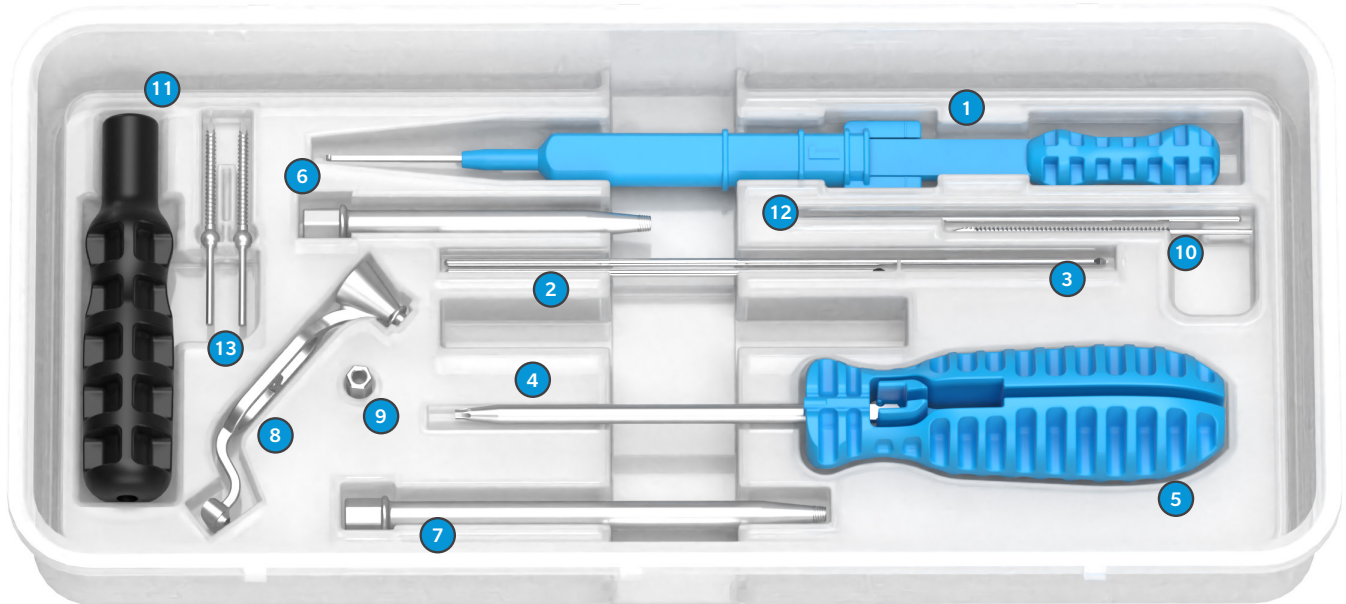
Part No.	Alt Part No.	Description
STRM-INST-KT-RS	INSTKTRS	STRATUM Reduced Size Standard Instrument Kit

Stratum RS

Reduced Size Foot Plating System

Standard Instrument Kit Base

Sterile/Disposable



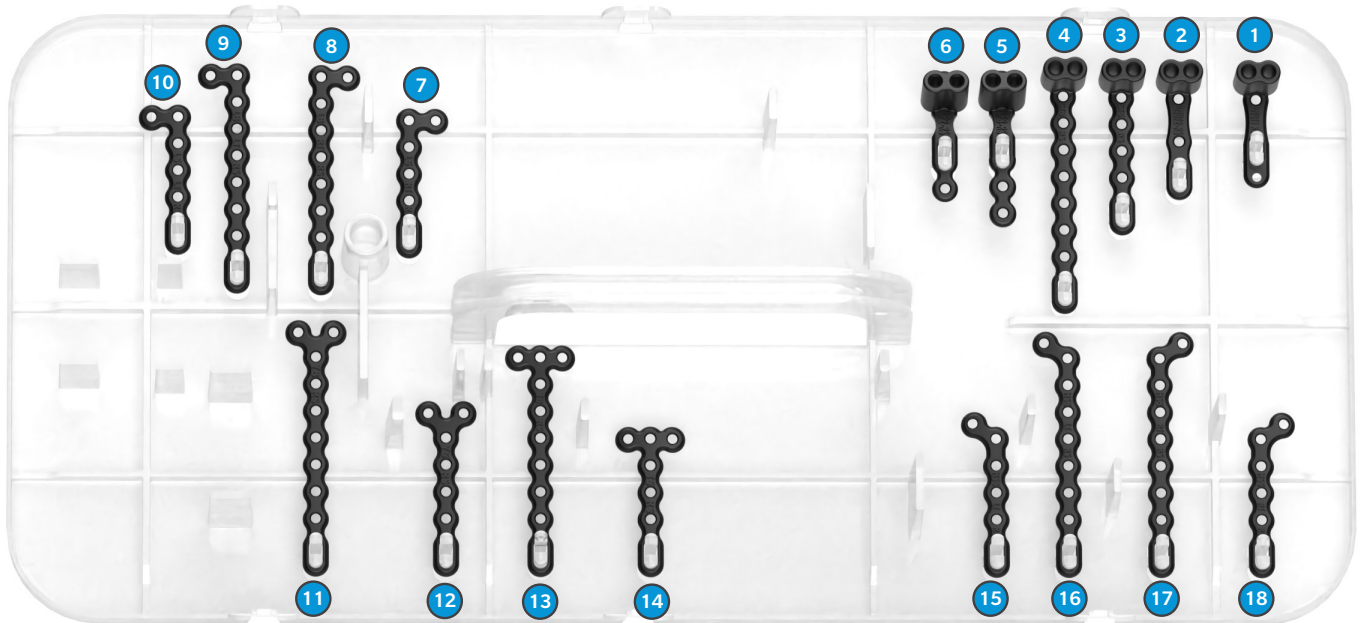
Item	Description
1	Depth Gauge
2	K-Wire - 2.0mm x 102mm
3	K-Wire - 2.0mm x 153mm
4	2.0mm Hex Driver
5	AO Driver Handle
6	Plate Bending Stick 80mm
7	Plate Bending Stick 110mm
8	Variable Angle Drill Guide
9	Threaded Nut
10	2.4mm Diameter Threaded Wire
11	Compression Nut Driver
12	K-Wire 1.6mm x 102mm
13	2.4mm Olive Wire

Stratum RS

Reduced Size Foot Plating System

Standard Template Lid

Sterile/Disposable



Item	Description	Item	Description
1	Peanut Plate Trial - 1 Hole	10	"L" Plate Trial - 5 Hole Left
2	Peanut Plate Trial - 2 Hole	11	"Y" Plate Trial - 8 Hole
3	Straight Plate Trial - 5 Hole	12	"Y" Plate Trial - 5 Hole
4	Straight Plate Trial - 8 Hole	13	"T" Plate Trial - 8 Hole
5	Single Lisfranc Plate Trial - 3 Hole	14	"T" Plate Trial - 5 Hole
6	Single Lisfranc Plate Trial - 2 Hole	15	"Hockey Stick" Plate Trial - 5 Hole Left
7	"L" Plate Trial - 5 Hole Right	16	"Hockey Stick" Plate Trial - 8 Hole Left
8	"L" Plate Trial - 8 Hole Right	17	"Hockey Stick" Plate Trial - 8 Hole Right
9	"L" Plate Trial - 8 Hole Left	18	"Hockey Stick" Plate Trial - 5 Hole Right

Stratum RS

Reduced Size Foot Plating System

Tine-Specific Plate Surgical Technique

The following technique describes key steps for all plates that are designed with tines in the Stratum RS Reduced Size Foot Plating System. This includes Single Lisfranc Fusion, Straight, and Peanut plates.

1. Plate Determination

After opening the standard instrumentation kit, turn the lid over to display all Trial Plate options. Select the desired Trial Plate that best fits the anatomy for the intended procedure. Place the Trial Plate on the bone and adjust to optimize plate position.



(Single Lisfranc Fusion plate used for Tine Plate technique)



2. Tines Preparation

Once Trial Plate is placed on bone, use pin driver to insert the short K-Wire bicortically through the bone using one of the guide tubes on the Trial Plate for alignment.

Note: Plate without tines do not require tine preparation. See Non-Tine Technique for detailed instructions.

Repeat with the long K-Wire into the second Guide Tube.

Stratum RS

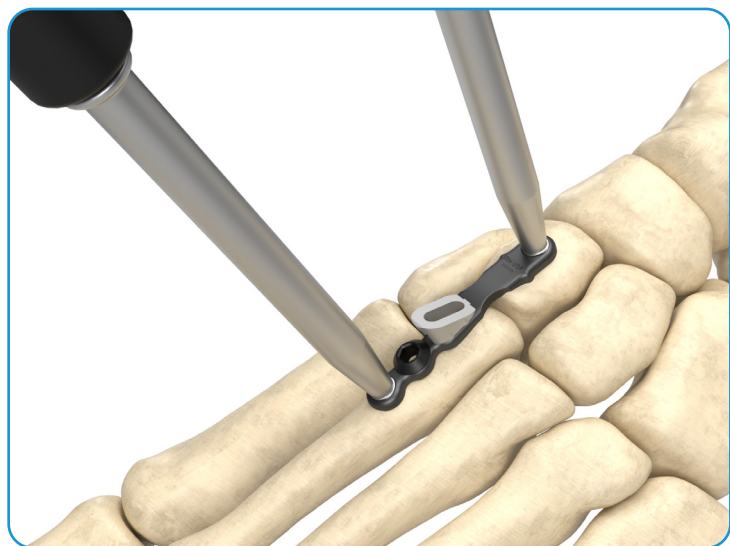
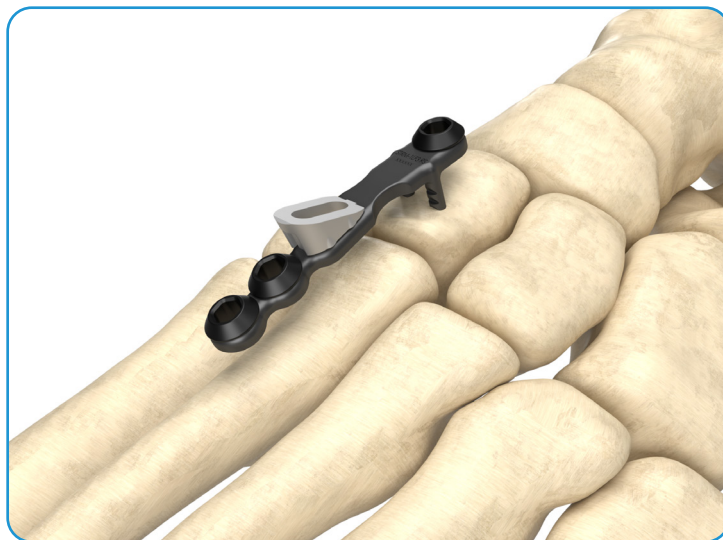
Reduced Size Foot Plating System

Tine-Specific Plate Surgical Technique

3. Plate Insertion

Remove both K-Wires and the Trial Plate noting the location of the holes. Open the corresponding plate and insert the tines into the prepared holes by hand, pressing plate down until flush with the bone.

Note: If bone is especially hard and additional force is required to fully insert the plate, a Bender can be threaded into the hole closest to the tines and lightly impacted to fully seat the plate, after temporarily removing the Alignment Cap.



4. Plate Contouring

OPTIONAL STEP - ONLY IF REQUIRED

Remove two Alignment Caps that are on either side of the plate region that requires contouring. Place alignment caps on back table for potential later use. Thread a Bender into the holes using the Compression Nut Driver. Slowly separate Benders until plate is contoured down to bone.

Note: Only bend plate once, do not bend back or bend a second time. Remove Benders and reassemble Alignment Caps or utilize variable angle drill guide for drilling technique of desired screw.

Stratum RS

Reduced Size Foot Plating System

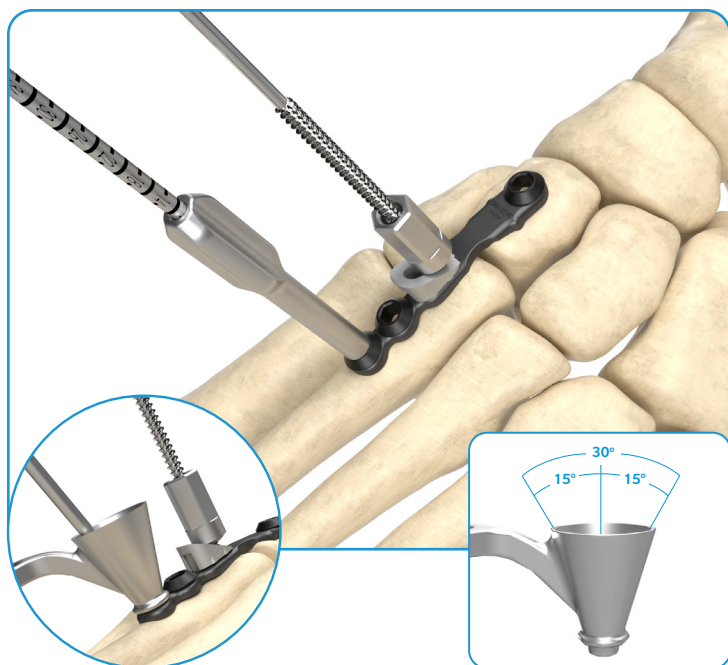
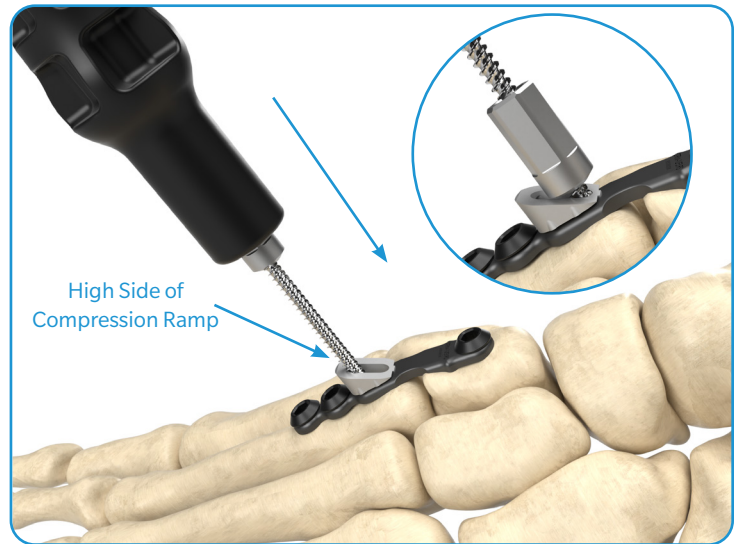
Tine-Specific Plate Surgical Technique

5. Compression

Reduce joint or fracture, then use the 1.6mm x 102mm K-Wire to create a pilot hole. Once pilot hole has been created, use a pin driver to insert the Threaded Wire into the ramp slot closest to the high side of the ramp. Drive the wire perpendicularly and bicortically into the bone. Use the inside edge of the ramp slot for alignment.

Thread the Compression Nut onto the 2.4mm diameter Threaded Wire until touching the ramp. Using the Compression Nut Driver, advance the Compression Nut down the Threaded Wire to compress the joint/fracture.

Stop turning the nut once desired compression across the joint/fracture is achieved.



6. Screw Preparation

While the Compression Ramp is holding compression, place the Drill Tube into an Alignment Cap that is on the same side of the joint/fracture as the Compression Ramp. With the appropriate Calibrated Drill, drill bicortically through the bone using the Drill Tube for alignment and measure off of the top of the Drill Tube.

Note: Variable angle non-Locking screws and multi-directional locking screws can be utilized as well in any hole by removing the Alignment Cap and utilizing the Variable Angle Drill Guide to guide the Drill Bit.

Screw can be placed 15 degrees off axis for a 30-degree cone of angulation.

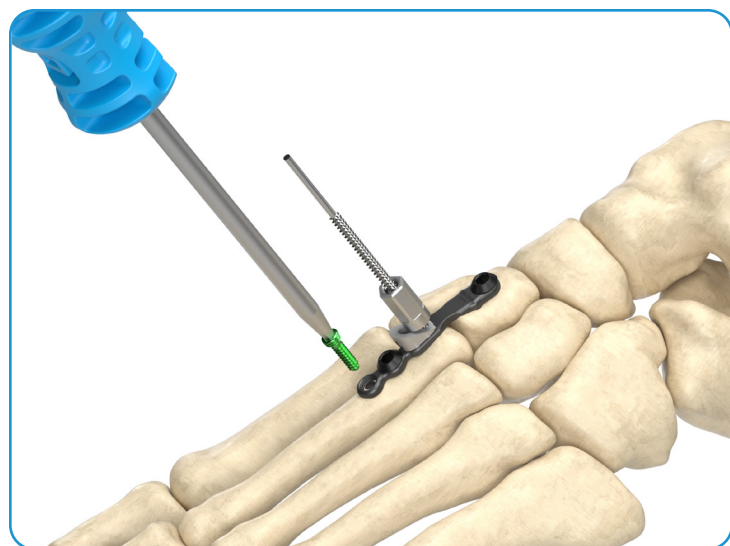
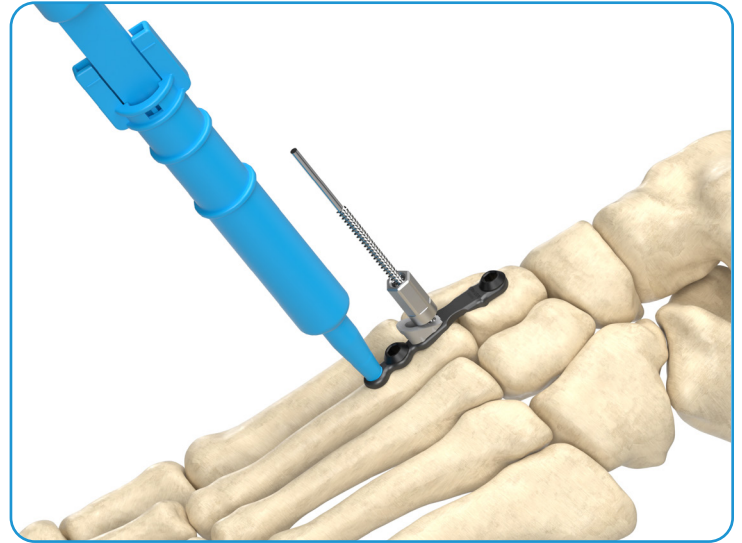
Stratum RS

Reduced Size Foot Plating System

Tine-Specific Plate Surgical Technique

7. Screw Determination

The screw length can be read directly off the calibrated drill bit at the top of the Drill Tube when the tip of the drill bit is positioned at the far cortex. Alternatively, use the Drill Tube to remove the Alignment Cap by unscrewing and use the Depth Gauge per standard technique.



8. Screw Insertion

If not already performed, unscrew the Alignment Cap with the Drill Tube from the Plate. Insert desired screw into the bone with supplied 2.0mm Hex Driver and Handle.

Note: If using power to insert screws, DO NOT fully seat the screw. Final seating of screws should be completed by hand and only with the supplied Driver and Handle.

Stratum RS

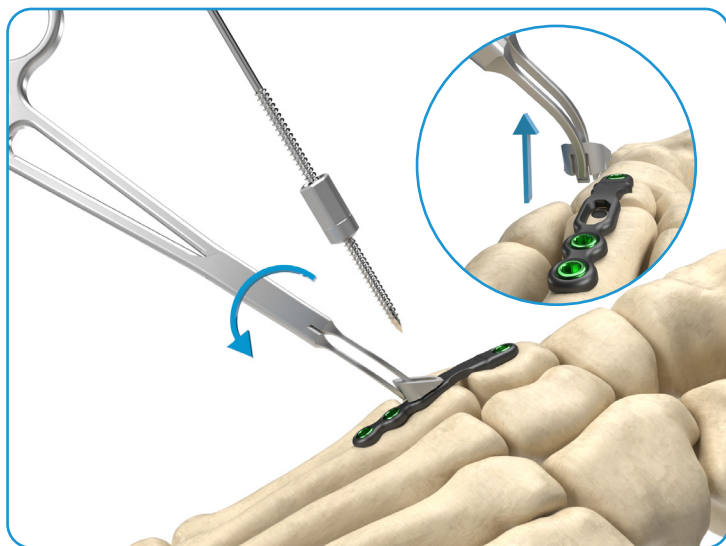
Reduced Size Foot Plating System

Tine-Specific Plate Surgical Technique

9. Additional Screws

Repeating the same process outlined previously, insert screws into any remaining open holes. **If a hole is left unfilled, the Alignment Cap must still be removed.**

Note: At least one screw is required on each side of the fixation site. Plate tines are not intended to be sole fixation on either side of fixation site.



10. Ramp Removal

With compression now held by inserted screws, the Compression Nut and the Threaded Wire can be removed with Compression Nut Driver and a standard pin driver. The Compression Ramp can then be removed by hand or with a standard hemostat. Place standard hemostat on tab at high side of the compression ramp and tilt clamp to inwardly press spring arm then roll compression ramp forward and up to remove.

*Hemostat not included

Stratum RS

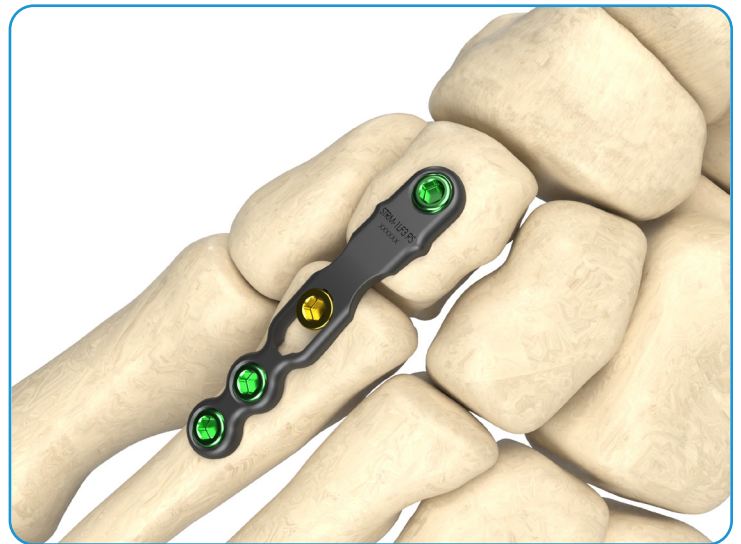
Reduced Size Foot Plating System

Tine-Specific Plate Surgical Technique

11. Slot Screw

Utilizing the hole made by the Threaded Wire as a pre-drill, insert the Depth Gauge to measure the length of screw required. Insert appropriate length 2.4mm Non-Locking Low-Profile Screw.

Prior to closure, ensure all remaining Alignment Caps have been removed from Plate.



12. Removal Technique

Use the 2.0mm Hex Driver to back-out all fixation screws.

Insert an elevator instrument* under the edge of the plate closest to the tines and lift tines out of the bone.

Once tines are lifted out of the bone, plate will be free to be removed.

*Not included

Stratum RS

Reduced Size Foot Plating System

Non-Tine Specific Plate Surgical Technique

The following technique describes key steps for all plates that are designed without tines in the Stratum RS Reduced Size Foot Plating System. This includes “Hockey Stick”, “L”, “T”, and “Y” plates.

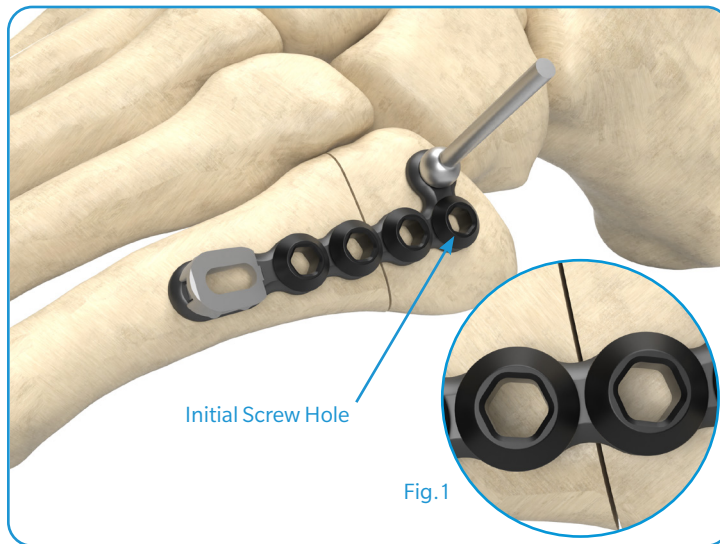
1. Plate Determination

After opening the standard instrumentation kit, turn the lid over to display all Trial Plate options. Select the desired Trial Plate that best fits the anatomy for the intended procedure. Place the Trial Plate on the bone and adjust to optimize plate position.

Note: Span fusion site with plate having a minimum of one screw hole on each side of fusion site.



(5-Hole Left “L” Plate used for Non-Tine Plate technique)



2. Plate Placement

Remove trial and place corresponding plate onto fusion site, ensuring that there is a minimum of one screw hole on each side of the fusion site. (See Fig. 1)

Note: An optional Olive Wire may be inserted to secure the Plate location. Remove Alignment Cap prior to insertion.

Once plate is secured, prepare the initial screw hole that is on the opposite side of the fusion site that the ramp is on. (See picture to the left) Follow the *Screw Preparation* step on page 12 for detailed instructions.

Stratum RS

Reduced Size Foot Plating System

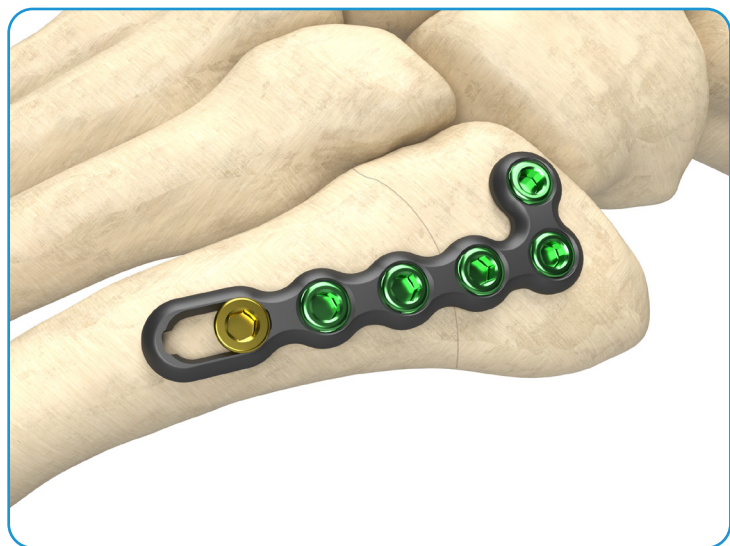
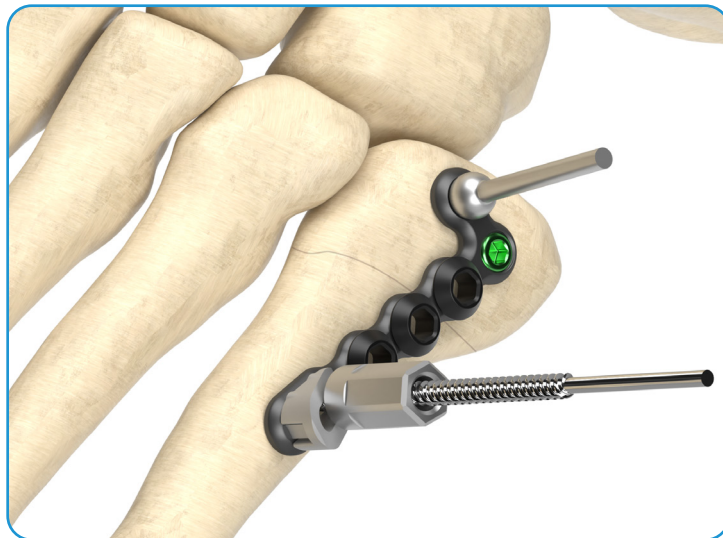
Non-Tine Specific Plate Surgical Technique

3. Screw Insertion and Compression

Once screw size has been determined, insert the initial screw per the *Screw Insertion* procedure described on page 13.

Note: If using power to insert screws, DO NOT fully seat the screw. Final seating of screws should be completed by hand and only with the supplied Driver and Handle.

After the initial screw has been placed, reduce the fusion site by following the *Compression* procedure on page 12.



4. Procedure Completion

Prepare screw holes and insert screws per technique. If an Olive Wire was used, it may be removed at this point and a screw can be inserted. Remove the Threaded Wire and Ramp per *Ramp Removal* procedure on page 14.

Once Ramp has been removed, insert a 2.4mm Non-Locking Low-Profile Screw into the hole.

Prior to closure, ensure all remaining Alignment Caps have been removed from Plate.

Stratum RS

Reduced Size Foot Plating System

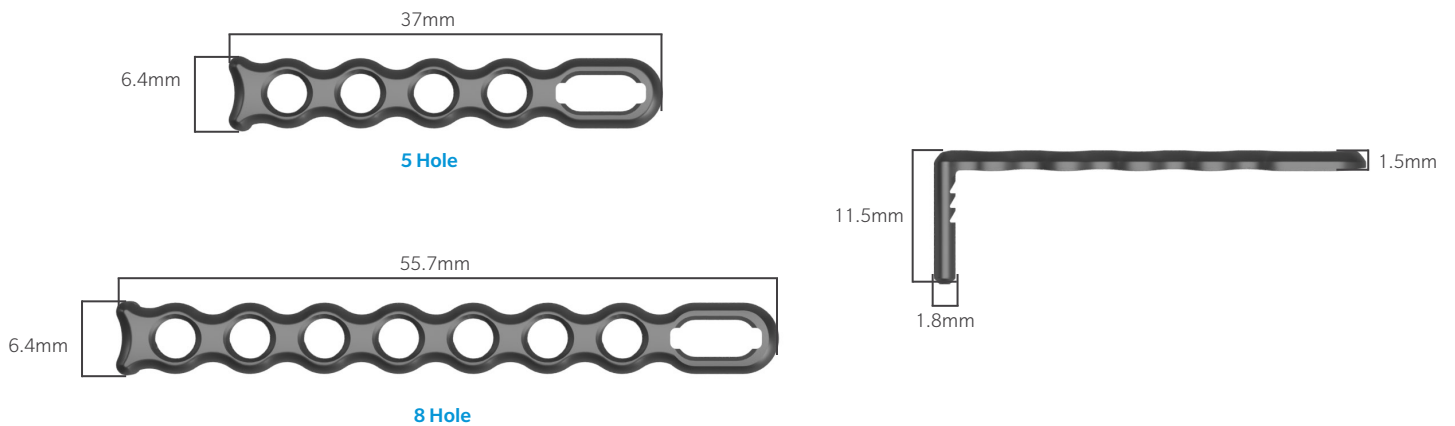
Plate Ordering Information

Part No.	Alt Part No.	Description
Straight Plates		
STRM-ST5-RS	ST5RS	STRATUM Reduced Size Straight Plate - 5 Hole
STRM-ST8-RS	ST8RS	STRATUM Reduced Size Straight Plate - 8 Hole
Peanut Plates		
STRM-PNUT1-RS	PNUT1RS	STRATUM Reduced Size Peanut Plate - 1 Hole
STRM-PNUT2-RS	PNUT2RS	STRATUM Reduced Size Peanut Plate - 2 Hole
Single Lisfranc Plates		
STRM-1LF2-RS	1LF2RS	STRATUM Reduced Size Single Lisfranc Fusion Plate - 2 Hole
STRM-1LF3-RS	1LF3RS	STRATUM Reduced Size Single Lisfranc Fusion Plate - 3 Hole
"Hockey Stick" Plates		
STRM-HS5-LT-RS	HS5LTRS	STRATUM Reduced Size "Hockey Stick" Plate - 5 Hole - Left
STRM-HS5-RT-RS	HS5RTRS	STRATUM Reduced Size "Hockey Stick" Plate - 5 Hole - Right
STRM-HS8-LT-RS	HS8LTRS	STRATUM Reduced Size "Hockey Stick" Plate - 8 Hole - Left
STRM-HS8-RT-RS	HS8RTRS	STRATUM Reduced Size "Hockey Stick" Plate - 8 Hole - Right
"L" Plates		
STRM-L5-LT-RS	L5LTRS	STRATUM Reduced Size "L" Plate - 5 Hole - Left
STRM-L5-RT-RS	L5RTRS	STRATUM Reduced Size "L" Plate - 5 Hole - Right
STRM-L8-LT-RS	L8LTRS	STRATUM Reduced Size "L" Plate - 8 Hole - Left
STRM-L8-RT-RS	L8RTRS	STRATUM Reduced Size "L" Plate - 8 Hole - Right
"T" Plates		
STRM-T5-RS	T5RS	STRATUM Reduced Size "T" Plate - 5 Hole
STRM-T8-RS	T8RS	STRATUM Reduced Size "T" Plate - 8 Hole
"Y" Plates		
STRM-Y5-RS	Y5RS	STRATUM Reduced Size "Y" Plate - 5 Hole
STRM-Y8-RS	Y8RS	STRATUM Reduced Size "Y" Plate - 8 Hole

Stratum RS

Reduced Size Foot Plating System Plate Ordering Information

Straight Plates



NOTE:

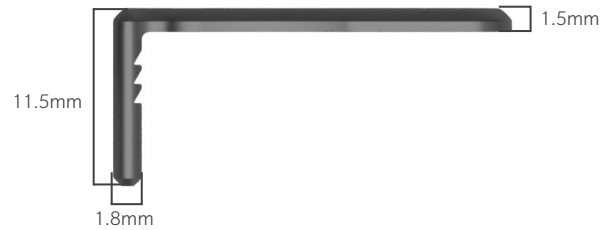
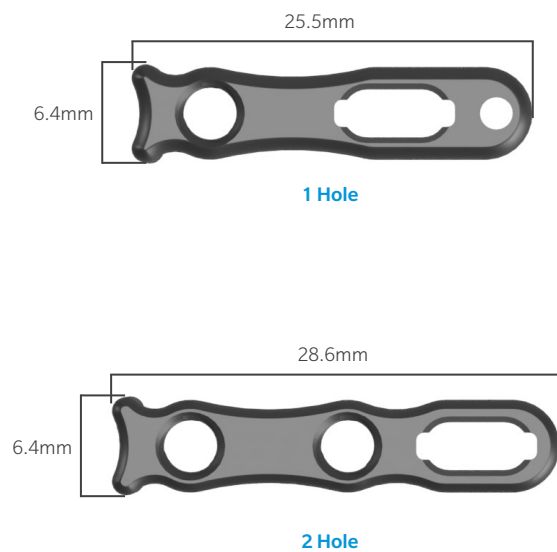
Trials included in Standard Instrument Kit (STRM-INST-KT-RS).

Part No.	Alt Part No.	Description
STRM-ST5-RS	ST5RS	STRATUM Reduced Size Straight Plate - 5 Hole
STRM-ST8-RS	ST8RS	STRATUM Reduced Size Straight Plate - 8 Hole

Stratum RS

Reduced Size Foot Plating System Plate Ordering Information

Peanut Plates



NOTE:

Trials included in Standard Instrument Kit (STRM-INST-KT-RS).

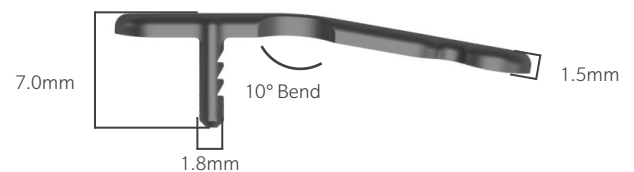
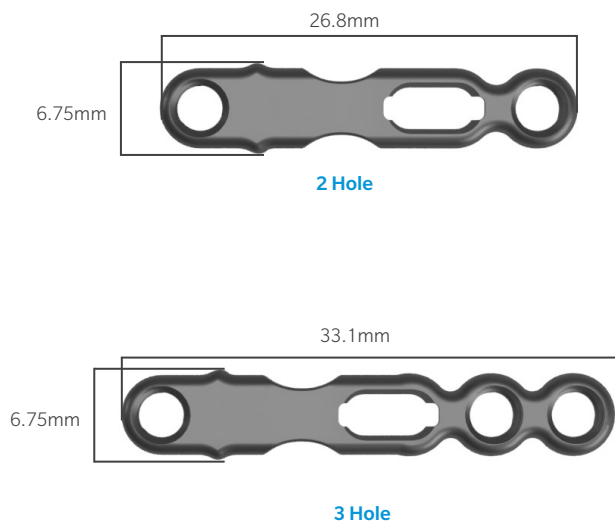
Part No.	Alt Part No.	Description
STRM-PNUT1-RS	PNUT1RS	STRATUM Reduced Size Peanut Plate - 1 Hole
STRM-PNUT2-RS	PNUT2RS	STRATUM Reduced Size Peanut Plate - 2 Hole

Stratum RS

Reduced Size Foot Plating System

Plate Ordering Information

Single Lisfranc Fusion Plates



NOTE:
Trials included in Standard Instrument Kit (STRM-INST-KT-RS).

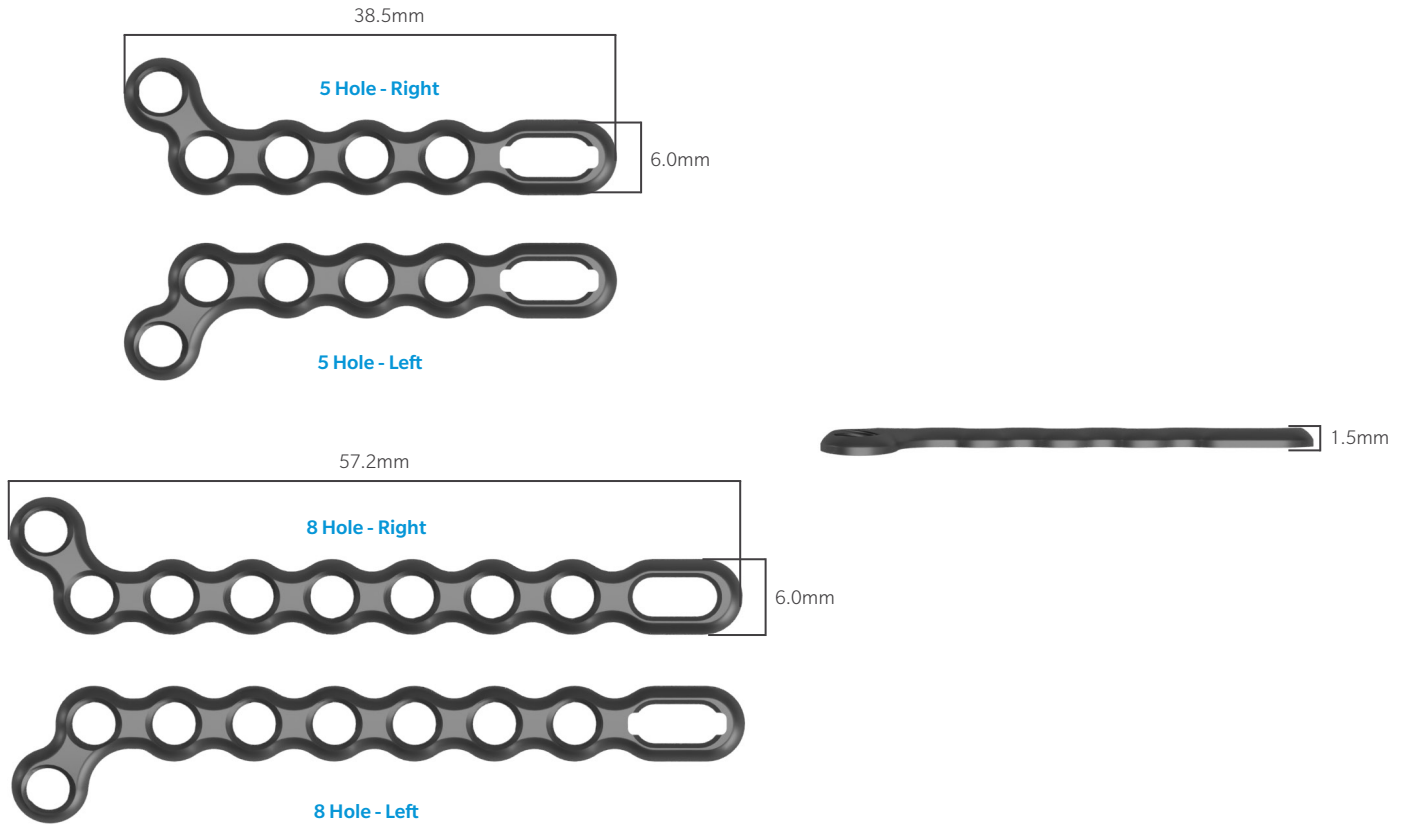
Part No.	Alt Part No.	Description
STRM-1LF2-RS	1LF2RS	STRATUM Reduced Size Single Lisfranc Fusion Plate - 2 Hole
STRM-1LF3-RS	1LF3RS	STRATUM Reduced Size Single Lisfranc Fusion Plate - 3 Hole

Stratum RS

Reduced Size Foot Plating System

Plate Ordering Information

“Hockey Stick” Plates



NOTE:

Trials included in Standard Instrument Kit (STRM-INST-KT-RS).

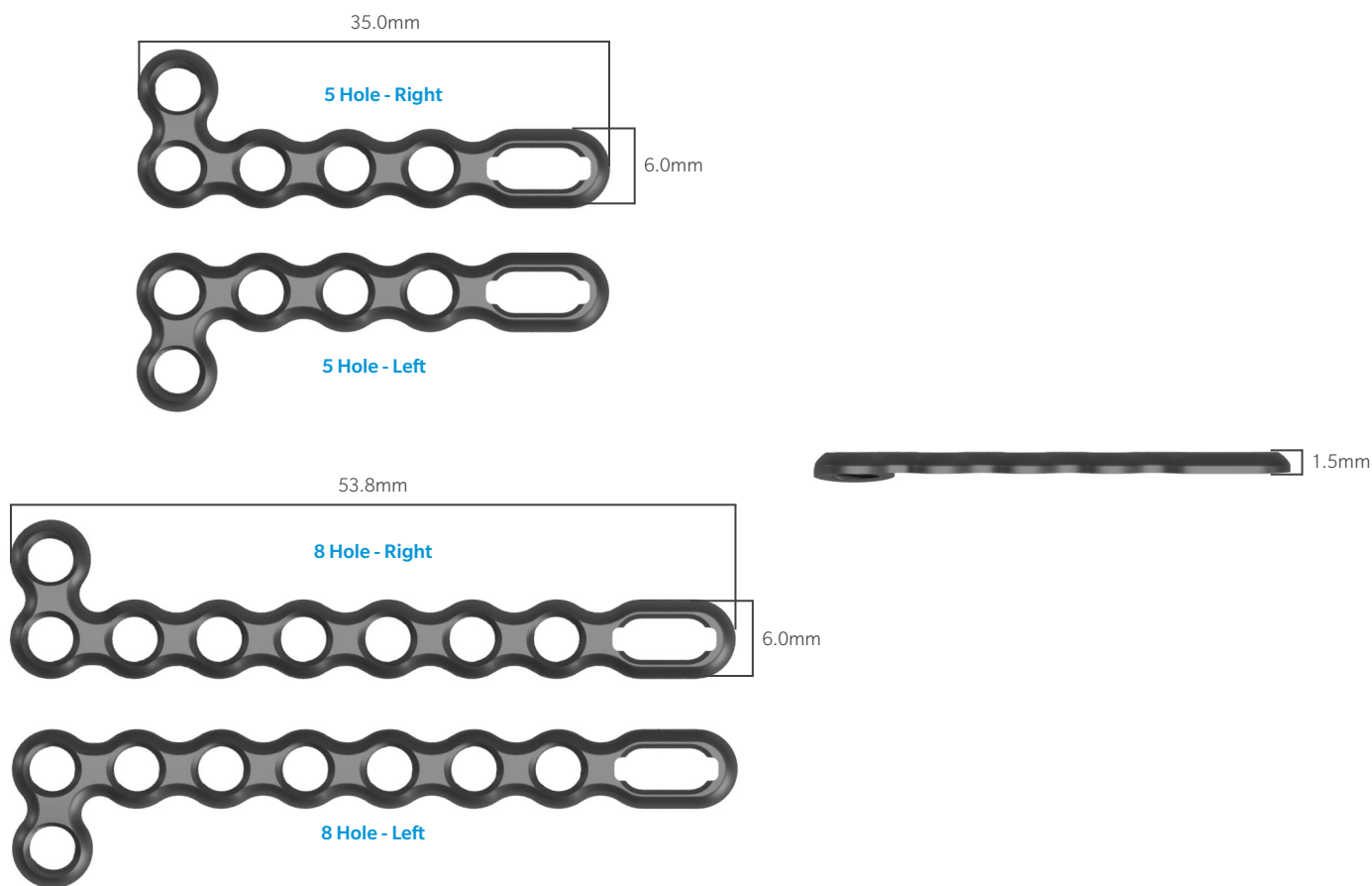
Part No.	Alt Part No.	Description
STRM-HS5-LT-RS	HS5LTRS	STRATUM Reduced Size “Hockey Stick” Plate - 5 Hole - Left
STRM-HS5-RT-RS	HS5RTRS	STRATUM Reduced Size “Hockey Stick” Plate - 5 Hole - Right
STRM-HS8-LT-RS	HS8LTRS	STRATUM Reduced Size “Hockey Stick” Plate - 8 Hole - Left
STRM-HS8-RT-RS	HS8RTRS	STRATUM Reduced Size “Hockey Stick” Plate - 8 Hole - Right

Stratum RS

Reduced Size Foot Plating System

Plate Ordering Information

“L” Plates



NOTE:

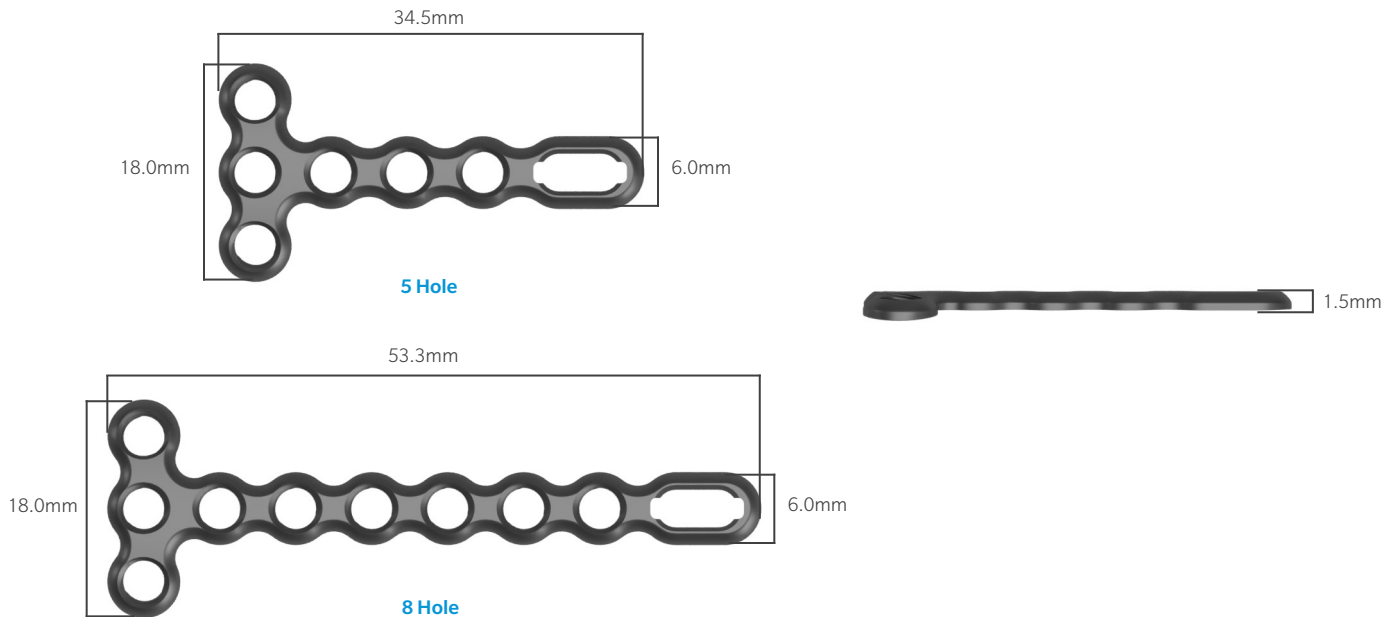
Trials included in Standard Instrument Kit (STRM-INST-KT-RS).

Part No.	Alt Part No.	Description
STRM-L5-LT-RS	L5LTRS	STRATUM Reduced Size “L” Plate - 5 Hole - Left
STRM-L5-RT-RS	L5RTRS	STRATUM Reduced Size “L” Plate - 5 Hole - Right
STRM-L8-LT-RS	L8LTRS	STRATUM Reduced Size “L” Plate - 8 Hole - Left
STRM-L8-RT-RS	L8RTRS	STRATUM Reduced Size “L” Plate - 8 Hole - Right

Stratum RS

Reduced Size Foot Plating System Plate Ordering Information

“T” Plates



NOTE:

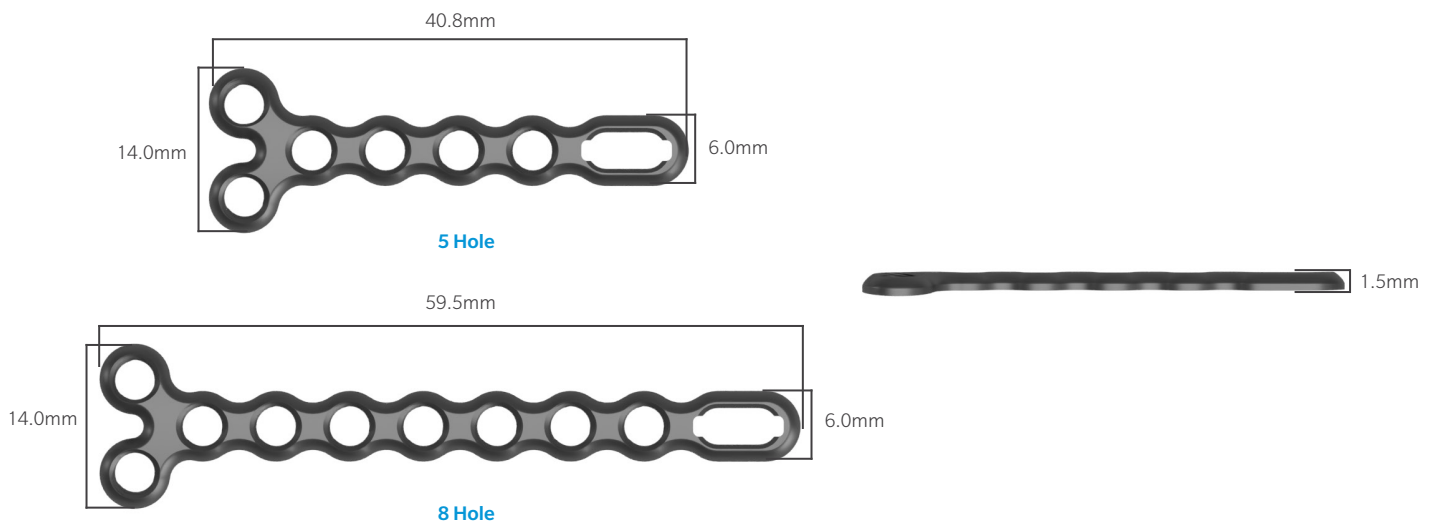
Trials included in Standard Instrument Kit (STRM-INST-KT-RS).

Part No.	Alt Part No.	Description
STRM-T5-RS	T5RS	STRATUM Reduced Size “T” Plate - 5 Hole
STRM-T8-RS	T8RS	STRATUM Reduced Size “T” Plate - 8 Hole

Stratum RS

Reduced Size Foot Plating System Plate Ordering Information

“Y” Plates



NOTE:

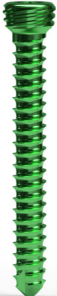
Trials included in Standard Instrument Kit (STRM-INST-KT-RS).

Part No.	Alt Part No.	Description
STRM-Y5-RS	Y5RS	STRATUM Reduced Size “Y” Plate - 5 Hole
STRM-Y8-RS	Y8RS	STRATUM Reduced Size “Y” Plate - 8 Hole


Stratum RS

Reduced Size Foot Plating System Sterile Screw Ordering Information

2.4mm Locking Screw

	Part No.	Alt Part No.	Description
	STRM-LK-2408RS-ST	LK2408RSST	STRATUM RS Locking Screw 2.4x8mm - Sterile
	STRM-LK-2410RS-ST	LK2410RSST	STRATUM RS Locking Screw 2.4x10mm - Sterile
	STRM-LK-2412RS-ST	LK2412RSST	STRATUM RS Locking Screw 2.4x12mm - Sterile
	STRM-LK-2414RS-ST	LK2414RSST	STRATUM RS Locking Screw 2.4x14mm - Sterile
	STRM-LK-2416RS-ST	LK2416RSST	STRATUM RS Locking Screw 2.4x16mm - Sterile
	STRM-LK-2418RS-ST	LK2418RSST	STRATUM RS Locking Screw 2.4x18mm - Sterile
	STRM-LK-2420RS-ST	LK2420RSST	STRATUM RS Locking Screw 2.4x20mm - Sterile
	STRM-LK-2422RS-ST	LK2422RSST	STRATUM RS Locking Screw 2.4x22mm - Sterile
	STRM-LK-2424RS-ST	LK2424RSST	STRATUM RS Locking Screw 2.4x24mm - Sterile
	STRM-LK-2426RS-ST	LK2426RSST	STRATUM RS Locking Screw 2.4x26mm - Sterile
	STRM-LK-2428RS-ST	LK2428RSST	STRATUM RS Locking Screw 2.4x28mm - Sterile
	STRM-LK-2430RS-ST	LK2430RSST	STRATUM RS Locking Screw 2.4x30mm - Sterile

2.4mm Non-Locking Low-Profile Screw


	Part No.	Alt Part No.	Description
	STRM-NL-2408RS-ST	NL2408RSST	STRATUM RS Non-Locking Screw 2.4x8mm - Sterile
	STRM-NL-2410RS-ST	NL2410RSST	STRATUM RS Non-Locking Screw 2.4x10mm - Sterile
	STRM-NL-2412RS-ST	NL2412RSST	STRATUM RS Non-Locking Screw 2.4x12mm - Sterile
	STRM-NL-2414RS-ST	NL2414RSST	STRATUM RS Non-Locking Screw 2.4x14mm - Sterile
	STRM-NL-2416RS-ST	NL2416RSST	STRATUM RS Non-Locking Screw 2.4x16mm - Sterile
	STRM-NL-2418RS-ST	NL2418RSST	STRATUM RS Non-Locking Screw 2.4x18mm - Sterile
	STRM-NL-2420RS-ST	NL2420RSST	STRATUM RS Non-Locking Screw 2.4x20mm - Sterile
	STRM-NL-2422RS-ST	NL2422RSST	STRATUM RS Non-Locking Screw 2.4x22mm - Sterile
	STRM-NL-2424RS-ST	NL2424RSST	STRATUM RS Non-Locking Screw 2.4x24mm - Sterile
	STRM-NL-2426RS-ST	NL2426RSST	STRATUM RS Non-Locking Screw 2.4x26mm - Sterile
	STRM-NL-2428RS-ST	NL2428RSST	STRATUM RS Non-Locking Screw 2.4x28mm - Sterile
	STRM-NL-2430RS-ST	NL2430RSST	STRATUM RS Non-Locking Screw 2.4x30mm - Sterile

Stratum RS

Reduced Size Foot Plating System

Sterile Screw Ordering Information

2.4mm Multi-Directional Screw

	Part No.	Alt Part No.	Description
	STRM-MDS-2408RS-ST	MDS2408RSST	STRATUM RS Multi-Directional Screw 2.4x8mm - Sterile
	STRM-MDS-2410RS-ST	MDS2410RSST	STRATUM RS Multi-Directional Screw 2.4x10mm - Sterile
	STRM-MDS-2412RS-ST	MDS2412RSST	STRATUM RS Multi-Directional Screw 2.4x12mm - Sterile
	STRM-MDS-2414RS-ST	MDS2414RSST	STRATUM RS Multi-Directional Screw 2.4x14mm - Sterile
	STRM-MDS-2416RS-ST	MDS2416RSST	STRATUM RS Multi-Directional Screw 2.4x16mm - Sterile
	STRM-MDS-2418RS-ST	MDS2418RSST	STRATUM RS Multi-Directional Screw 2.4x18mm - Sterile
	STRM-MDS-2420RS-ST	MDS2420RSST	STRATUM RS Multi-Directional Screw 2.4x20mm - Sterile
	STRM-MDS-2422RS-ST	MDS2422RSST	STRATUM RS Multi-Directional Screw 2.4x22mm - Sterile
	STRM-MDS-2424RS-ST	MDS2424RSST	STRATUM RS Multi-Directional Screw 2.4x24mm - Sterile
	STRM-MDS-2426RS-ST	MDS2426RSST	STRATUM RS Multi-Directional Screw 2.4x26mm - Sterile
	STRM-MDS-2428RS-ST	MDS2428RSST	STRATUM RS Multi-Directional Screw 2.4x28mm - Sterile
	STRM-MDS-2430RS-ST	MDS2430RSST	STRATUM RS Multi-Directional Screw 2.4x30mm - Sterile

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Disposables Ordering Information

Part No.	Alt Part No.	Description
Disposable Drill Bits		
STRM-DRL-20-RS	DRL20RS	STRATUM Reduced Size Calibrated Drill 2.0mm Sterile with Sleeve
Drivers		
STRM-TL-DRV-RS	TLDRVRS	STRATUM Reduced Size Torque Limiting 2.0mm Hex Driver - Sterile
STRM-DRV-HEX-2MM	DRVHEX2MM	STRATUM Screw Driver Hex 2mm -Sterile
Component		
TDWIRE-NUT-RS	TDWIRENUTRS	STRATUM Reduced Size 2.4mm Threaded Wire and Nut - Sterile
TD-OLV-WIRE-PK	TDOLVWIREPK	STRATUM 2.4mm Threaded Olive Wires - 2 Pack
Disposable Kit		
STRM-INST-KT-RS	INSTKTRS	STRATUM Reduced Size Standard Instrument Kit



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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 Stratum RS Reduced Size Foot Plating System is manufactured using Ti-6Al-4V ELI and Co-Cr-Mo.



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