

Ortholoc™ SPS

Shoulder Plating System

Operative technique



with 3DSi Technology

Ortholoc SPS

Shoulder Plating System

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This publication sets forth detailed recommended procedures for using Stryker devices and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

Important

- The patient should be advised that the device cannot and does not replicate a normal healthy bone, that the device can break or become damaged as a result of strenuous activity or trauma and that the device has a finite expected service life.
- Removal or revision of the device may be required sometime in the future.
- Cleaning and sterilization information is provided in the applicable instructions for use.
- Non-sterile devices, including implants and instruments, must be cleaned and sterilized prior to use, in accordance with validated methods.
- Devices that are able to be disassembled should be disassembled prior to point-of-use processing. Additionally, devices with movable components that do not facilitate disassembly should be manually articulated during the point-of-use processing step in order to evacuate additional soils.
- Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.
- Consult Instructions for Use (<https://ifu.wright.com>) for a complete list of potential adverse effects and adverse events, contraindications, warnings and precautions.
- The surgeon must advise patients of surgical risks, and make them aware of adverse effects and alternative treatments.
- An implant whose packaging is open or damaged or whose expiration date has passed must not be used. Every precaution must be taken to ensure sterility when opening the packaging of the implant and during implantation.

Ortholoc SPS system overview

Accurate calcar screw placement is critical for preventing varus head collapse, one of the most common complications when using a proximal humerus plate. Considering varying patient anatomies, plate malposition is also a concern—a screw could be placed outside of the calcar, or the acromion may be impinged if the plate is positioned too high.

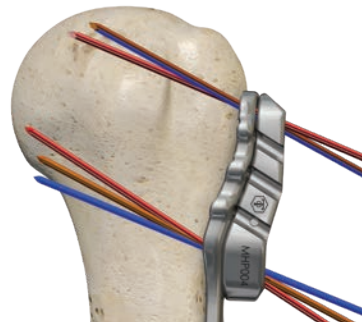
The Ortholoc SPS Shoulder Plating System addresses these challenges with a system designed for accuracy, adjustability, and anchoring. By focusing first on accurate medial calcar support, the Ortholoc SPS allows you to fine-tune and adjust the plate and screw positions. Additionally, three calcar screws anchor the plate to allow for head fixation.



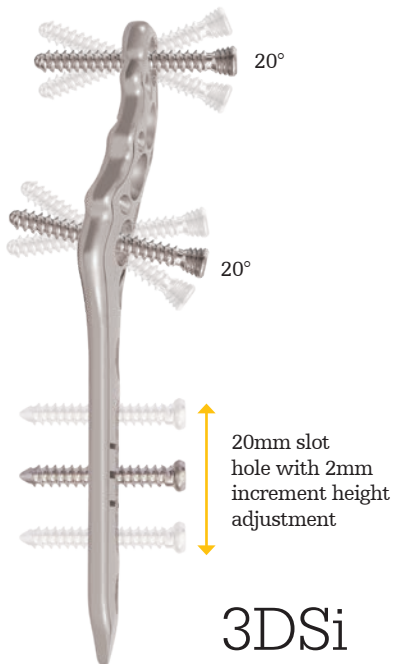
Three anatomic guide blocks based on head size to aid in accurate medial calcar targeting.

Designed for accuracy.

A calcar first technique, the Ortholoc SPS allows calcar screw placement with three anatomic guide blocks that offer different screw patterns according to the patient anatomy.



Three anatomic guide blocks (small/medium/large) designed to accurately target the medial calcar according to the head size.



Designed for adjustability.

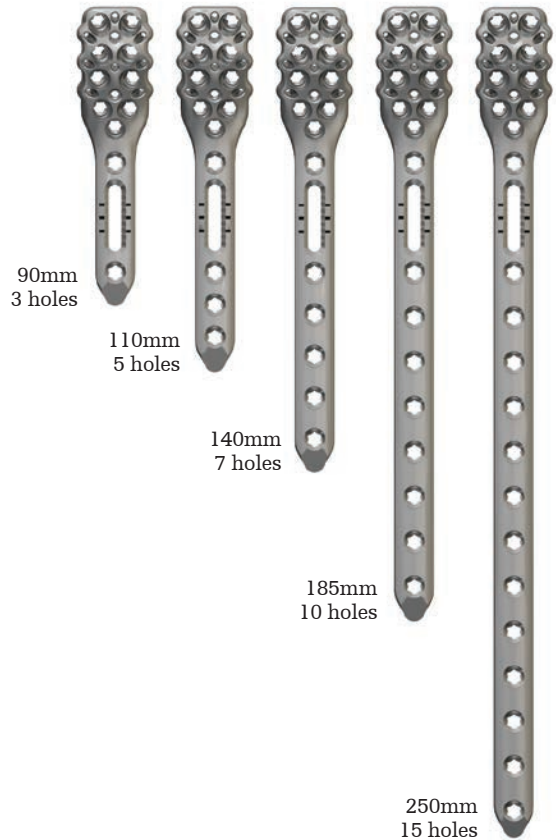
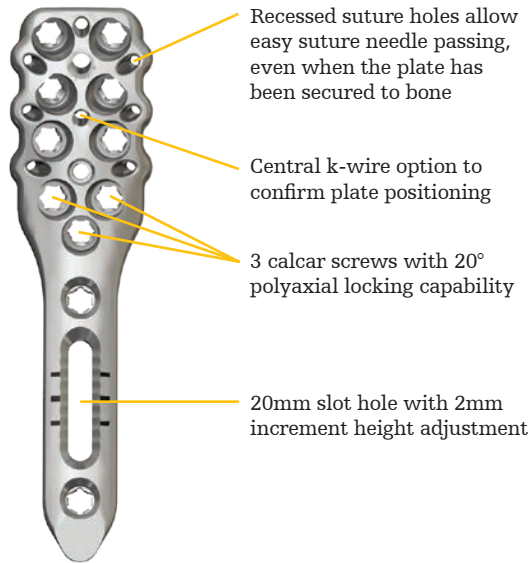
The Ortholoc SPS features a 20mm slot hole for further height adjustment with 2mm increments. Additionally, if the guide block system does not provide the desired screw placement, a manual polyaxial drill guide can be used to alter the direction of the locking screws with 20° angulation thanks to 3DSi polyaxial locking screw technology.

Designed for anchoring.

With three calcar screws, the Ortholoc SPS offers reliable and strong fixation. Furthermore, the anatomic guide blocks place the screws at the periphery of the humeral head to purchase harder bone and to prevent direct articular surface perforation.



Plate and screw offering



Standard plates

- 9 proximal screw holes with polyaxial locking screw capability
- 7 proximal suture holes to help maintain fracture reduction
- 5 plate lengths ranging from 90mm (3 shaft holes) to 250mm (15 shaft holes) to accommodate a wide variety of fracture patterns



GT plate

- Designed to address isolated greater tuberosity fractures
- 53mm long (4 shaft holes)
- Bendable plate for an anatomical bone contour
- 8 suture holes
- Lateral deltoid split approach may be preferable, but care must be taken to protect the axillary nerve

Posterior plates

- Designed to further capture the greater tuberosity and counterforce the pull-off of the infraspinatus preventing post-operative greater tuberosity migration
- Right and left plate 105mm long (4 shaft holes)
- 2 posterior bendable branches for an anatomical bone contour
- Lateral deltoid split approach may be preferable, but care must be taken to protect the axillary nerve

Blunt Tip



Screws

- T-15 screw head design
- 3.5mm locking blunt-tipped screw (length 18-54mm)
- 3.5mm locking cortical screws (length 18-40mm)
- 3.5mm non-locking cortical screws (length 18-50mm)

Indications for use

The Ortholoc SPS Shoulder Plating System is indicated for:

- Fractures and fracture dislocations, osteotomies, and non-unions of the proximal humerus, particularly in osteopenic bone.

Contraindications

- Acute or chronic infectious diseases of any etiology and localization.
- Unsuitable or insufficient bone support preventing proper fixation of the osteosynthesis devices.
- Inadequate tissue coverage.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or operative site.
- Neuromuscular or mental disorders which might jeopardize fixation and postoperative care.
- Bone immaturity.
- Children in the growth phase.
- Known allergy to one of the materials.
- Pregnancy.
- Particular degenerative diseases where osteosynthesis devices must be considered only as means of temporary relief or slowing down disease progress.
- Other medical or surgical conditions which would preclude the potential benefit of surgery.

Side-effects and possible complications

- Infection.
- Tissue reaction.
- Dissociation of components.
- Changes in length of the operated limb.
- Breakage of the component as a result of abnormal or changes of activity, and reduction in the range of motion.
- Delayed bone healing.
- Nonunion.
- Malunion.
- Necrose.
- Possibility of reaction to the metal.
- Some side-effects may require a revision of the involved osteosynthesis devices.
- The deterioration of the device after osseous reconsolidation cannot be regarded as a dysfunction or a deterioration of the characteristics of the material.
- Some complications and side-effects may stem from a lack of awareness of the precautions for use.

Operative technique

Patient positioning

The use of fluoroscopy is recommended in all cases.

Proper patient positioning and fluoroscopy is critical to ensure the fracture can be adequately visualized.

Patient is placed in a beach chair position with the shoulder off the table and the fluoroscopy in place.

Standard delto-pectoral or a deltoid-split approach may be used.

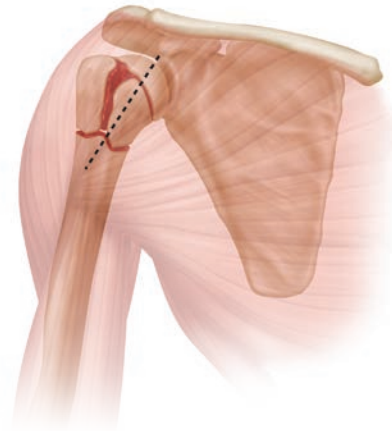


Surgical approach

Delto-pectoral approach

Locate and mark the coracoid process and the axis of the humeral shaft and begin a 12–14cm incision laterally between these two landmarks. Care is taken to ensure that the incision is not crossing the anterior axillary fold. The delto-pectoral interval is developed and the cephalic vein is usually retracted laterally.

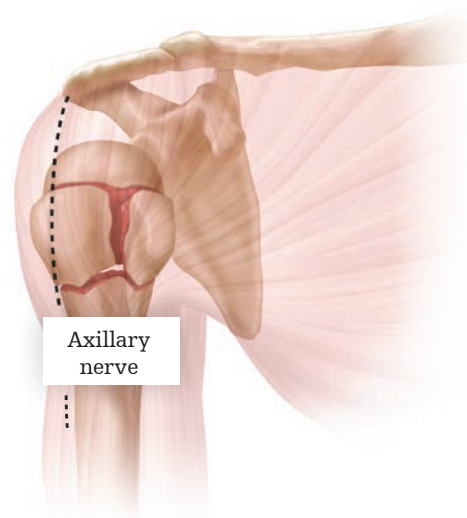
Retract the coracobrachialis medially and the deltoid laterally, taking care not to injure the axillary and musculocutaneous nerves. Identify the pectoralis insertion at the floor of the delto-pectoral interval. If necessary, release the proximal third of the pectoralis tendon for better exposure. Develop the subacromial space and mobilize the proximal deltoid with deltoid retractor if desired.



Deltoid-split approach

The deltoid is split from the lateral border of the acromion. The incision may not extend more than 5cm distally to the acromion, to protect the axillary nerve. The axillary nerve must be identified and carefully protected. The nerve is usually located approximately 6-7cm from the acromion.

Two soft-tissue windows are created through the deltoid above and below the area where the axillary nerve passes. The upper window is used for fracture reduction, plate insertion and insertion of proximal screws into the plate. The lower window is used to ensure the plate is properly seated on the shaft of the humerus and to allow insertion of the shaft screws.



Note:

Delto-pectoral approach is the recommended approach with the posterior and GT plate since it offers an easier posterior bone fragment management. To position calcar screws, the superior window is used with the shoulder in abduction to make calcar screw holes visible without stretching axillary nerve.

Operative technique

Fracture reduction

Proper reduction of the fracture is key for good bone healing and function.

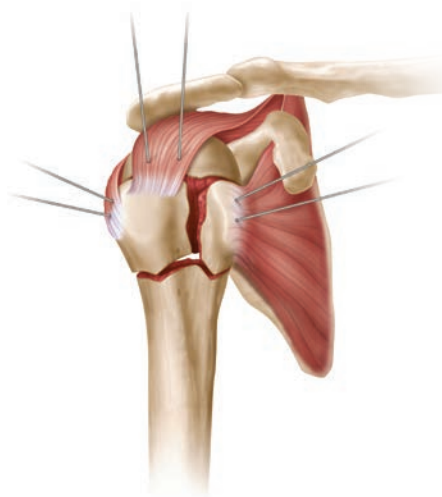
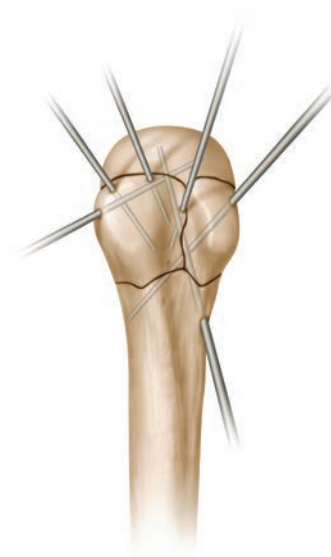
Reduce the humeral head fragments using traction, manipulation or your preferred technique.

K-wires may be used to manipulate and temporarily fix the bone fragments, and then confirm proper reduction using fluoroscopy. K-wires may be also placed through the screw holes or central holes of the plate.

High strength sutures such as Niceloop or Force Fiber may also be placed into the cuff-tuberosity junction to mobilize, identify and tag the fractured greater and/or lesser tuberosity for eventual securing to plate through suture holes.

Note:

Niceloop is not available in Canada.



Operative technique

Plate and screw placement overview

Delto-pectoral approach



1. Initial placement with medium guide block



2. Target calcar



3. Confirm size/adjust height/lock placement



4. Drill first cortex



5. Gauge



6. Screw placement



7. For additional proximal screws, repeat steps 4-5-6



8. For additional shaft screws, use the 2.5 drill

Operative technique

Deltoid-split approach



1. Initial placement with medium guide block



2. Temporary fixation



3. Target calcar in abduction to avoid axillary nerve



4. Confirm size/adjust height/lock placement



5. Drill first cortex in abduction



6. Gauge in abduction



7. Screw placement in abduction



8. For additional proximal screws, repeat steps 4-5-6 in neutral position



9. For additional shaft screws, use the 2.5 drill in neutral position

Operative technique

Initial plate placement

Ortholoc SPS guiding system

Place the medium guide block onto the standard plate. Using the T-15 hex driver bit and ratcheting AO driver, attach the medium guide block to the standard plate.

Note:

Do not use the torque limiting driver to attach the guide blocks to the plate. Doing so may result in guide block screw breakage.

The Threaded 2.5mm drill bit sleeve can be used as a handle to aid in placing the plate.

Position approximately 10mm down from the greater tuberosity.

A center-center wire can also be used to help position the plate on the humerus.

For this, place a k-wire through the center hole of the plate.

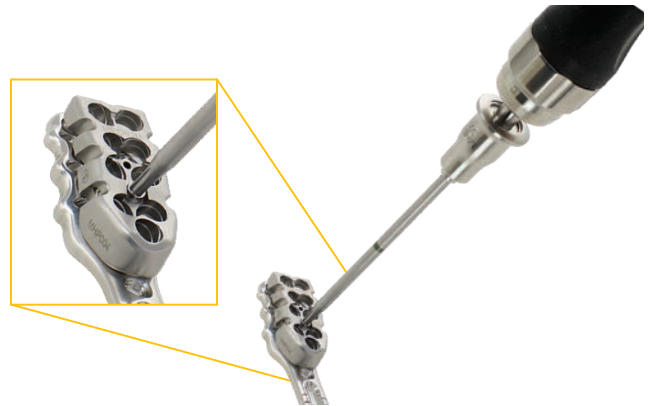
Confirm plate position with fluoroscopy in both antero-posterior and medio-lateral views.

Once proper position is achieved, align the handled slot drill guide with the center line of the slot. Use the 2.5mm drill bit to drill down through the handled slot drill guide and drill a bicortical hole through the shaft.

Remove the handled slot drill guide. Use the depth gauge to determine the length of screw needed. Place a cortical non-locking screw into the hole and use the T-15 hex driver bit to tighten down.

Note:

Do not seat the screw with power. The ratcheting driver handle should be used for placing the cortical non-locking screw. If the screw is not fully tightened, it will still allow for some height adjustment of the plate before placing any locking screws and being committed to placement.



Operative technique

Target medial calcar and superior cortex

Place a 3.5mm screw sleeve into the anterior superior hole and the medial calcar hole of the guide block. Place 1.6mm pin sleeves into the screw sleeves. Pass a 1.6mm trocar pin through pin sleeves. This will be driven in just deep enough to be able to use x-ray to assess the location and size of the necessary guide block.

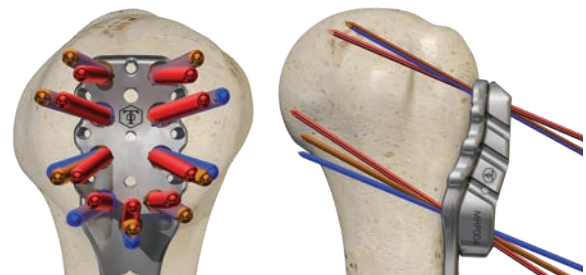


Note:

The slot screw may be loosened to allow for further height adjustment of the plate to a more desired location.

If the assessment shows that the superior screw is too high, then a small guide block may be needed. If the assessment shows that the medial calcar and superior screw is too low, then a large guide block may be needed.

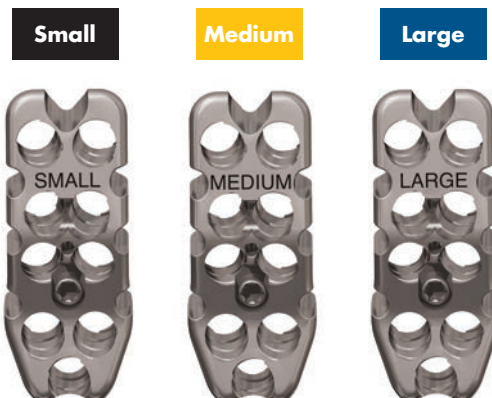
If the guide block is changed out for a different size, a new x-ray image will be required to determine and confirm plate placement.



Screw patterns based on patient anatomy.

Note:

Do not use the torque limiting driver to attach the guide blocks to the plate. Doing so may result in guide block screw breakage.



Three anatomic guide blocks (small/medium/large) to target accurately the medial calcar head size to target medial calcar and peripheral head support.

Operative technique

Proximal screw placement

Note:

Blunt-tipped screws are recommended for proximal use to reduce the risk of articular surface perforation.

Remove the 1.6mm trocar pins and the 1.6mm pin sleeves.

Place 2.5mm drill sleeves into the screw sleeves.

Through the 2.5 drill sleeve, place the 2.5mm drill bit and drill through the first cortical wall.

Note:

The drill is able to go deeper into the bone if necessary, but it is only recommended to perforate the first cortex to avoid articular surface perforation.

After drilling through the first cortical wall, use the screw length gauge to determine the length of screw needed for proximal fixation.

Place the gauge down through the screw sleeve and press the probe until resistance is met.

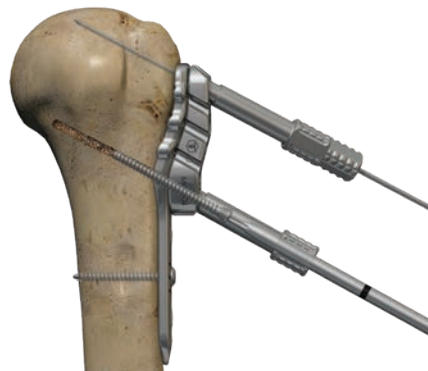
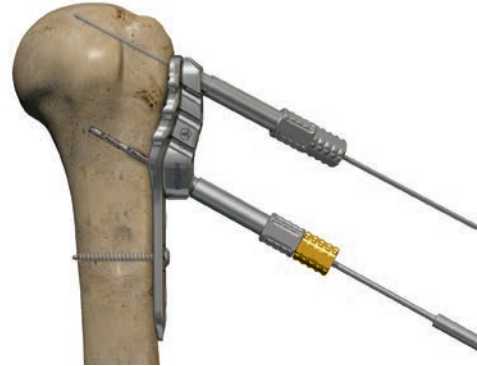
Once resistance is met the probe should be pressing against the subchondral bone. The corresponding screw length can then be read at the back end of the screw length gauge.

Note:

The screw length gauge measures in 2mm increments. Downsize to a shorter screw to reduce the risk of primary cut out.

After determining the length of screw necessary, place the screw into the appropriate screw sleeve and use the T-15 hex driver bit.

The driver bit may be driven with power, the ratcheting driver handle or the torque limiting driver.



Operative technique

Note:

Do not seat the screw with power.

If power is used, drive the T-15 hex driver bit down until the laser-marked circumferential line is at the entry point of the screw sleeve. Once the line has reached the screw sleeve, disconnect the power driver and change over to the ratcheting driver handle to finish driving until snug. Screw will be finished tight using the torque limiting handle once all screws have been placed.



Repeat the "Proximal screw placement" step to finish placing all the proximal screws into the humeral head.

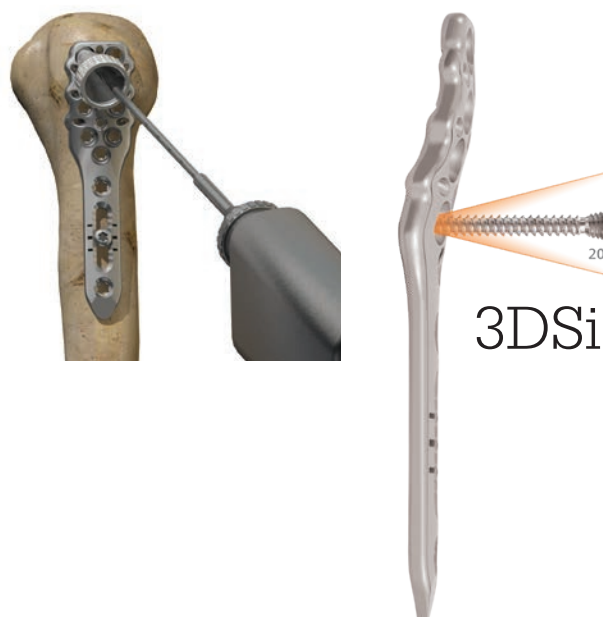


Note:

If the guide block system does not provide the desired screw placement, the manual polyaxial drill guide can be used to alter the direction of the locking or non-locking screws.

The polyaxial drill guide has threads so that it can be screwed into the threaded locking holes of the plates. This provides a stable drill guide to work through.

The polyaxial drill guide may be used for a proximal screw or a distal shaft screw. Both screws will require the use of the 2.5mm drill bit.



Operative technique

To use additional shaft screws, place the threaded 2.5mm drill bit sleeve in the hole and use the 2.5mm drill bit through the drill sleeve to drill a bicortical hole through the shaft. Remove the drill sleeve and use the depth gauge to determine the length of cortical screw needed. Place a cortical screw into the hole and use the T-15 hex driver bit to tighten down.



Note:

If bone voids remain after bone fragments reduction, Pro-Dense may be injected into voids/gaps that are not intrinsic to the stability of the skeletal system. The Pro-Dense paste cured in situ provides a void/gap filler that can augment the provisional hardware. The cured paste acts as a temporary support media and is not intended to provide structural support during the healing process.

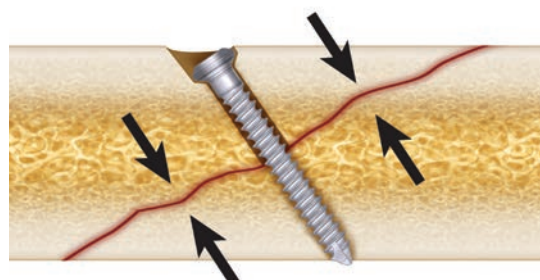


Note:

In the case a cortical screw is needed to compress two bone fragments outside of the plate (lag technique), use the 2.5mm drill bit to drill a bicortical hole. Then, use the 3.5mm drill bit to drill the first cortical wall only. Use the countersink tool to prepare a bone socket to ensure full contact with the screw head. Determine screw length with the depth gauge. Place the screw into the hole and use the T-15 hex driver bit to tighten down.



Countersink tool for Lag technique.



Operative technique

Posterior plate

If the posterior plate is used, the posterior branches can be bent using two threaded plate benders. Follow the “Screw placement” steps to insert the two posterior proximal screws into the greater tuberosity. Pay attention not to conflict with the other proximal screws already in place.

The aim of the posterior screws is to counteract the pull-off force of the infraspinatus ensuring a stronger posterior fixation and preventing from post-operative migration of the greater tuberosity.

Note:

Deltoid-split approach is recommended with the posterior plate since it offers an easier posterior bone fragment management.



GT plate for isolated greater tuberosity fracture

In the case of an isolated greater tuberosity fracture requiring fixation with a plate, reduce the bone fragments using your preferred technique (k-wires, sutures, etc.).

Place a 3.5mm screw sleeve into the plate to help position the GT plate approximately 10mm down from the top of the greater tuberosity.

If needed, bend the distal portion of the plate to get an anatomic bone contour using two threaded plate benders.

Follow the “Screw placement” steps to place all the necessary screws into the humerus.

Note:

Deltoid-split approach is recommended with the GT plate since it offers an easier posterior bone fragment management.



Operative technique

Suturing technique

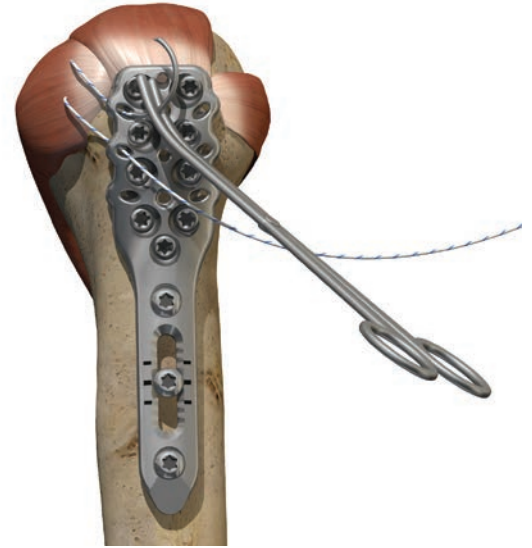
The plate has recessed suture holes that allow the passage of suture needles even after the plate has been secured to the bone.

High strength sutures such as Niceloop or Force Fiber can be passed first through the cuff-tuberosity junction and then through the suture holes of the plate or first through the suture holes of the plate and then through the cuff-tuberosity junction.

The sutures can be then attached to the plate by tying a knot.

Note:

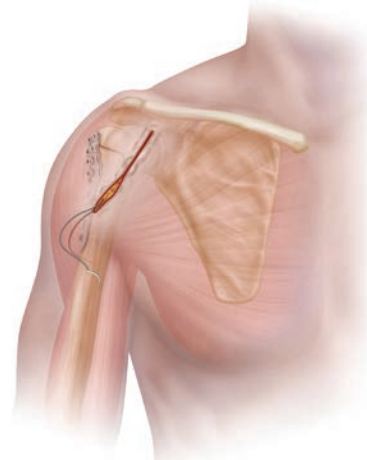
Niceloop is not available in Canada.



Closure

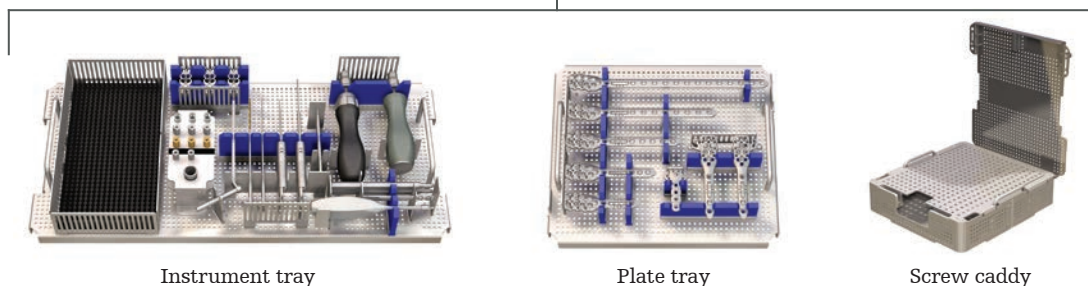
Copiously irrigate the wound and close the wound in layers.

In the deltoid-split approach, meticulous repair of the deltoid split is important to avoid deltoid dehiscence. Direct transosseous suturing of the deltoid to the acromion can be recommended.



Ordering Information

One case



Instrument tray

Plate tray

Screw caddy

Catalog # YKAD007

Includes plates and screws

Instruments

Included in YKAD007

Catalog #	Description
MHP002	Ortholoc SPS small guide block
MHP004	Ortholoc SPS medium guide block
MHP006	Ortholoc SPS large guide block
MHP007	Ortholoc SPS Ø3.5mm screw sleeve
MHP009	Ortholoc SPS Ø1.6mm pin sleeve
MHP010	Ortholoc SPS handled slot drill guide
MHP011	Ortholoc SPS threaded Ø2.5mm drill bit sleeve
MHP012	Ortholoc SPS torque limiting driver
MHP013	Ortholoc SPS Ø3.5mm drill bit
MHP014	Ortholoc SPS screw length gauge
MHP015	Ortholoc SPS depth gauge
MHP016	Ortholoc SPS Ø2.5mm drill bit
MHP017	Ortholoc SPS countersink tool
MHP018	Ortholoc SPS polyaxial drill guide
MHP019	Ortholoc SPS ratcheting AO driver handle
MHP020	Ortholoc SPS threaded plate bender
MHP021	Ortholoc SPS Ø1.6 x 150mm trocar pin
MHP022	Ortholoc SPS T-15 hex driver bit
MHP028	Ortholoc SPS implant tray
MHP030	Ortholoc SPS screw caddy
MHP031	Ortholoc SPS 2.5mm drill sleeve

Ordering information

Blunt-tipped locking screw (stainless steel, non-sterile)

Included in YKAD007

Catalog #	Description
SPS418	3.5 Blunt-tipped locking screw X 18mm
SPS420	3.5 Blunt-tipped locking screw X 20mm
SPS422	3.5 Blunt-tipped locking screw X 22mm
SPS424	3.5 Blunt-tipped locking screw X 24mm
SPS426	3.5 Blunt-tipped locking screw X 26mm
SPS428	3.5 Blunt-tipped locking screw X 28mm
SPS430	3.5 Blunt-tipped locking screw X 30mm
SPS432	3.5 Blunt-tipped locking screw X 32mm
SPS434	3.5 Blunt-tipped locking screw X 34mm
SPS436	3.5 Blunt-tipped locking screw X 36mm
SPS438	3.5 Blunt-tipped locking screw X 38mm
SPS440	3.5 Blunt-tipped locking screw X 40mm
SPS442	3.5 Blunt-tipped locking screw X 42mm
SPS444	3.5 Blunt-tipped locking screw X 44mm
SPS446	3.5 Blunt-tipped locking screw X 46mm
SPS448	3.5 Blunt-tipped locking screw X 48mm
SPS450	3.5 Blunt-tipped locking screw X 50mm
SPS452	3.5 Blunt-tipped locking screw X 52mm
SPS454	3.5 Blunt-tipped locking screw X 54mm

T-15



3.5mm

Cortical locking screw (stainless steel, non-sterile)

Included in YKAD007

Catalog #	Description
SPS118	3.5 Cortical locking screw X 18mm
SPS120	3.5 Cortical locking screw X 20mm
SPS122	3.5 Cortical locking screw X 22mm
SPS124	3.5 Cortical locking screw X 24mm
SPS126	3.5 Cortical locking screw X 26mm
SPS128	3.5 Cortical locking screw X 28mm
SPS130	3.5 Cortical locking screw X 30mm
SPS132	3.5 Cortical locking screw X 32mm
SPS134	3.5 Cortical locking screw X 34mm
SPS136	3.5 Cortical locking screw X 36mm
SPS138	3.5 Cortical locking screw X 38mm
SPS140	3.5 Cortical locking screw X 40mm

T-15



3.5mm

Ordering information

Cortical non-locking screw (stainless steel, non-sterile)

Included in YKAD007

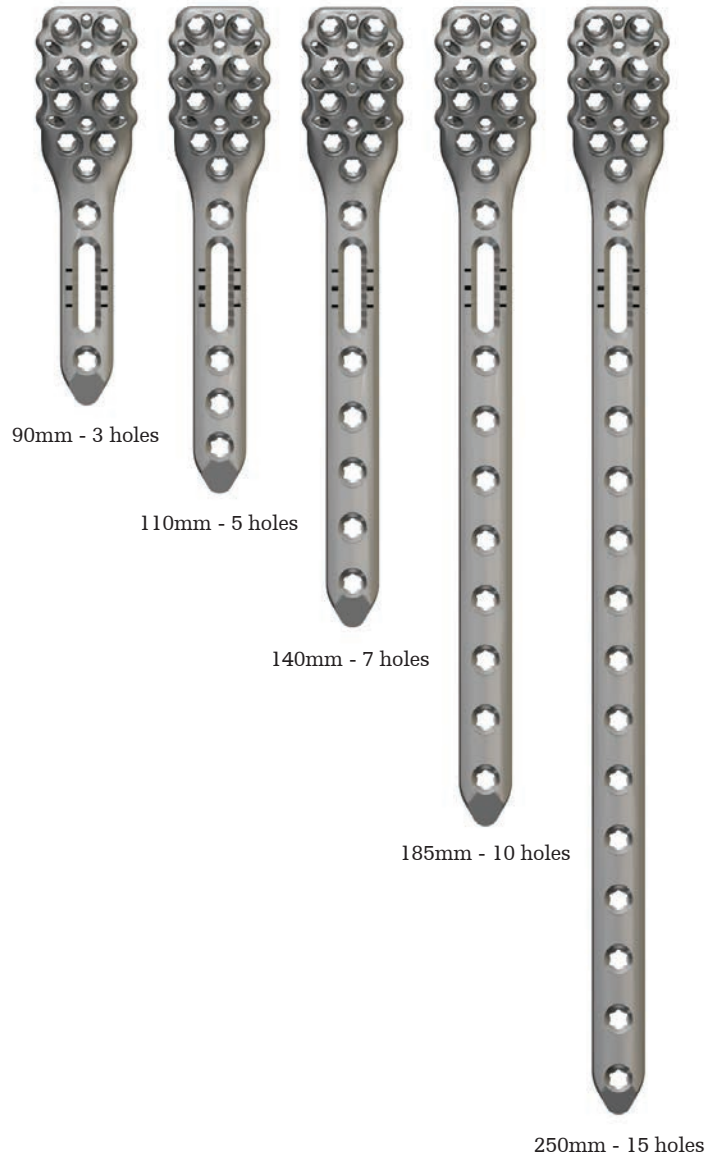
Catalog #	Description
SPS218	3.5 Cortical non-locking screw X 18mm
SPS220	3.5 Cortical non-locking screw X 20mm
SPS222	3.5 Cortical non-locking screw X 22mm
SPS224	3.5 Cortical non-locking screw X 24mm
SPS226	3.5 Cortical non-locking screw X 26mm
SPS228	3.5 Cortical non-locking screw X 28mm
SPS230	3.5 Cortical non-locking screw X 30mm
SPS232	3.5 Cortical non-locking screw X 32mm
SPS234	3.5 Cortical non-locking screw X 34mm
SPS236	3.5 Cortical non-locking screw X 36mm
SPS238	3.5 Cortical non-locking screw X 38mm
SPS240	3.5 Cortical non-locking screw X 40mm
SPS242	3.5 Cortical non-locking screw X 42mm
SPS244	3.5 Cortical non-locking screw X 44mm
SPS246	3.5 Cortical non-locking screw X 46mm
SPS248	3.5 Cortical non-locking screw X 48mm
SPS250	3.5 Cortical non-locking screw X 50mm

T-15



3.5mm

Ordering information



Standard plate (stainless steel, non-sterile)

Included in YKAD007

Catalog #	Description
SPS003	Standard 3 hole - 90mm Plate
SPS005	Standard 5 hole - 110mm Plate
SPS007	Standard 7 hole - 140mm Plate
SPS010	Standard 10 hole - 185mm Plate
SPS015	Standard 15 hole - 250mm Plate

Ordering information

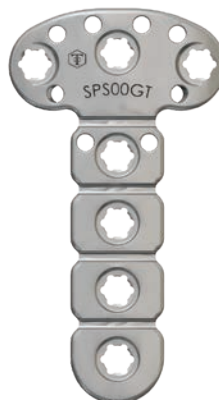


105mm - 4 holes

Posterior 4 hole plate (stainless steel, non-sterile)

Included in YKAD007

Catalog #	Description
SPS004R	Posterior 4 hole - 105mm plate - right
SPS004L	Posterior 4 hole - 105mm plate - left



53mm - 4 holes

Greater tuberosity plate (stainless steel, non-sterile)

Included in YKAD007

Catalog #	Description
SPS00GT	Greater tuberosity plate - 53mm

Ordering information



Pro-Dense*

Catalog #	Description	Needle
87SR-0070	Pro-Dense injectable regenerative graft 7cc	13 gauge
87SR-0120	Pro-Dense injectable regenerative graft 12cc	13 gauge

*Pro-Dense may not be available in all geographies.

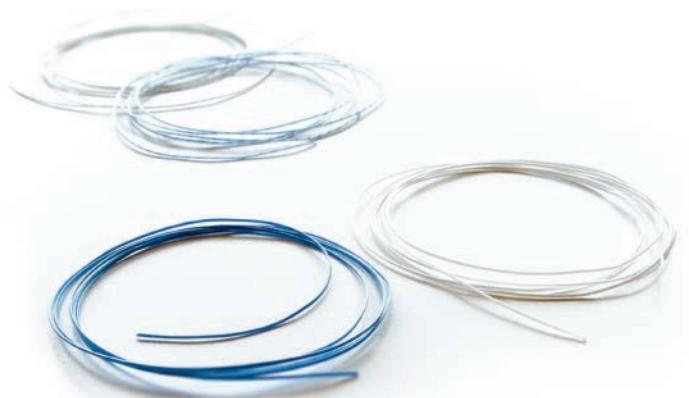


Niceloop

Catalog # single pack	Catalog # 12 Pack	Size	Length	Color	Needle
SMSL50101	SMSL50103	Size 5	36"	Green	KAC-25
SMSL50201	SMSL50203	Size 5	36"	White	KAC-25
SMSL50301	SMSL50303	Size 5	36"	White/Green	KAC-25

Note:
Niceloop is not available in Canada.

Ordering Information



Force Fiber

Catalog # single pack	Catalog # 12 pack	Size	Length	Color	Needle
SMS100101S	SMS100101	Size 2	36"	White/Blue	K-Point
SMS100201S	SMS100201	Size 2	36"	White/Black	K-Point
SMS100501S	SMS100501	Size 2	36"	White/Blue	Tapered
SMS100601S	SMS100601	Size 2	36"	White/Black	Tapered
SMS101901S	SMS101901	Size 2	36"	Blue	Two needles HC-5 - C-12
SMS100701S	SMS100701	Size 3-4	36"	White/Blue	Tapered
SMS100801S	SMS100801	Size 3-4	36"	White/Black	Tapered
SMS100301S	SMS100301	Size 3-4	36"	White/Blue	Diamond-point
SMS100401S	SMS100401	Size 3-4	36"	White/Black	Diamond-point
SMS101601S	SMS101601	Size 5	36"	White/Blue	K-60
SMS101701S	SMS101701	Size 5	36"	White/Black	K-60
SMS101801S	SMS101801	Size 5	36"	White	K-60

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The information presented is intended to demonstrate a Stryker product. A surgeon must always refer to the package insert, product label and/or instructions for use, including the instructions for cleaning and sterilization (if applicable), before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

The instructions for use, operative techniques, cleaning instructions, patient information leaflets and other associated labeling may be requested online at ifu.wright.com or wright.com. If saving the instructions for use, operative techniques, cleaning instructions from the above mentioned websites, please make sure you always have the most up to date version prior to use.

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Manufactured by:

Tornier, Inc.
10801 Nesbitt Avenue So.
Bloomington, MN 55437
USA

stryker.com