RAPHAEL™

POSTERIOR LUMBAR MINIMALLY
INVASIVE FIXATION PLATFORM

SURGICAL TECHNIQUE GUIDE

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PRODUCT OVERVIEW

The RAPHAEL™ open fixation platform consists of polyaxial screws, dual lead screw threading, various rods, and locking set screws to provide efficient and secure top-loading, rigid fixation in posterior lumbar fusions.

SYSTEM FEATURES AND BENEFITS

- 16mm and 25mm tulip heights available for up to 8mm of rod reduction
- 5.0mm locking hex set screw to provide efficient and secure top-loading, rigid fixation
- A 2.3mm pitch and 4.6mm lead on a dual lead thread
- 5.5mm titanium rods available in straight and curved
- Cortical screw pattern available for maximum purchase

SYSTEM SPECIFICATIONS
SCREWS

Polyaxial Screws

RAPHAEL II™ Screws | Diameter: 5.5mm, Color: Green

TYPE	LENGTH*(mm)	PART NUMBER
Standard	35	015.3037
	40	015.3042
	45	015.3047
	50	015.3052
	55	015.3057
Cannulated	35	015.4637
	40	015.4642
	45	015.4647
	50	015.4652
	55	015.4657

RAPHAEL II™ Screws | Diameter: 6.5mm, Color: Gold

TYPE	LENGTH*(mm)	PART NUMBER
Standard	35	015.3237
	40	015.3242
	45	015.3247
	50	015.3252
	55	015.3257
Cannulated	35	015.4837
	40	015.4842
	45	015.4847
	50	015.4852
	55	015.4857

RAPHAEL II™ Screws | Diameter: 7.5mm, Color: Fushia

TYPE	LENGTH*(mm)	PART NUMBER
Standard	35	015.3437
	40	015.3442
	45	015.3447
	50	015.3452
	55	015.3457
Cannulated	35	015.5037
	40	015.5042
	45	015.5047
	50	015.5052
	55	015.5057

RAPHAEL II™ Screws | Diameter: 8.5mm, Color: Light Blue

TYPE	LENGTH*(mm)	PART NUMBER
Standard	40	015.3642
	45	015.3647
	50	015.3652
	55	015.3657
	60	015.3662
Cannulated	40	015.3643
	45	015.3648
	50	015.3653
	55	015.3658
	60	015.3663

Polyaxial-Cortical Screws

RAPHAEL II™ : 5.5 mm Diameter Screws

TYPE	LENGTH*(mm)	PART NUMBER
Standard	30	115.1430
	35	115.1435
	40	115.1440
	45	115.1445
	50	115.145
	55	115.1455

Note: Monoaxial screws available upon request.

INSTRUMENTATION

K-WIRES

100.7009	K-Wire, Round Tip, L480mm, D1.4, Nitinol
100.7015	K-Wire Holder, L=500 mm

DILATORS

016.7011	Dilator, ID1.8 x OD10mm
016.7012	Dilator, ID10 x OD14mm
016.7014	Dilator, ID14 x OD17mm (L=130, R)

DRILLS

019.7024	Drill, Cannulated, 1/4" Square QC, D3.4mm

016.7024	Drill, Cannulated, Trilobe End, D3.4mm (for Power Tool)

TAPS

119.7037	Tap, Cannulated, 1/4" Square QC, 5.5
119.7038	Tap, Cannulated, 1/4" Square QC, 5.5
119.7039	Tap, Cannulated, 1/4" Square QC, 5.5
119.7040	Tap, Cannulated, 1/4" Square QC, 5.5

SCREW DRIVERS

016.7100	Hex Driver, Cannulated, 1/4" Square QC, 4.0 Self-Retention
019.7050	Hex Driver MIS, 1/4" Square QC, 4.0, Ratcheting
019.7150	Hex Driver MIS, 1/4" Square QC, 4.0, Ratcheting

ROD INSTRUMENTS

016.7051	Rod Inserter
129.7051	Rod Inserter (Straight)

MISCELLANEOUS

015.7051	Alignment Tool, Polyaxial Screw
100.7031	Caliper, Ball Tip, 35-230mm

SET SCREW DRIVERS

100.7250	Hex Driver, Ball-Handle, Self-Retention, 5.0
019.7062	Hex Driver, 1/4" Square QC, 5.0 with Shoulder
016.7064	Anti-Torque Device

PIN CUTTER

016.7072	Cutter, Sleeve, Type 2
100.7013	Cutter, Pin

HANDLES

100.2021	T-Handle, 1/4"Square QC (OL-Ortholynx)
100.2003	Straight Handle, Ratcheting, 1/4" Square QC, Cannulated
100.2029	T-Handle, Ratcheting, 1/4"Square QC, Cannulated
100.2023	T-Handle, Torque Limiting, 1/4" Square QC (12 N-m)
100.2001	Straight Handle, Ratcheting, 1/4" Square QC
100.2025	T-Handle, Ratcheting, 1/4' Square QC

SURGICAL TECHNIQUE
POSITIONING AND PREPARATION

Patient Positioning

Step 1

Locate the pedicles and remove bone and/or soft tissue as needed with standard instruments

Surgical Site Preparation

Step 2

Use the Awl to perforate the cortical bone.

Step 3

Use a Curved/Straight Probe to create a pedicle pathway. Probes are marked every 10mm to help determine the correlating screw length.

Note: All probes have graduated markings 30mm - 60mm in10mm increments.

Step 4

Use a Curved/Straight Sounder to palpate for any perforations in the pedicle wall.

Note: All Sounders have graduated markings 10mm - 60 mm in 10mm increments. The marking between 40mm - 50mm is filled.

Step 5 (Optional)

RAPHAEL™ Screws are self- tapping, however pedicles may be tapped. Use the tap with correlating screw diameter to tap the pedicle pathway the desired length.

Note: The diameter of the taps are equal to the diameter of the screw and is marked every 5mm to indicate depth.

Step 6

Drill (016.7021 Drill, Trilobe End, D3.4mm) can be used with a power tool. Starting depth of 30mm with increments of 5mm up to 65mm.

Figure 1
Patient positioning

SCREW PLACEMENT

Screw Insertion

Step 1

Attach the Hex Driver (016.7100 Hex Driver, 1/4" Square QC, 4.0, Self-Retention) to a Handle (100.2001 Straight Handle Ratcheting, 1/4" Square QC Bradshaw Or 100.2025 T-Handle, Ratcheting, 1/4" Square QC Bradshaw), then insert the Hex Driver into the head of a pedicle screw. Insert the Pedicle Screw into the vertebral body into desired position.

Screw Alignment

Step 1

Alignment of the pedicle screw tulip may be achieved using a Multi-Function Tool (Alignment, Rod Pusher, Sleeve Cutter) (015.7102 Multi-Function Tool (Alignment, Rod Pusher, Sleeve Cutter))

Rod Placement

Step 1

To make changes to the contour of the rod, select an appropriate bend radius and place the rod between the rollers of the Rod Bender (100.7011 Rod Bender). Compress the rod bender until the desired contour is achieved.

Note: In-situ benders (015.7763 Rod Bender, In-Situ, Left or 015.7764 Rod Bender, In-situ, right) are also provided for more fine-tune contouring.

Step 2

The rod is placed into the construct using the Rod Holding Forceps (015.7067 Rod Holding Forceps).

Note: Avoid creating a sharp bend or undoing a contour in the rod, as this may lead to premature material fatigue of the implant. Do not bend the rod in the reverse direction, as this may introduce micro factures that compromise its strength. If reverse rod bending has occured the bent rod must be discarded.

Step 3

The Multi-Function Tool (Alignment, Rod Pusher, Sleeve Cutter) is used to apply gentle force to the rod while engaging the set screw.

Step 4

The Rod Fork is designed to straddle the implant and rod while introducing the rod into the open implant.

Set Screw Insertion

Step 1

The Retractor is used to make space for the Hex Driver with Handle, 5.0 (100.7550 Hex Driver, 1/4" Square QC, Self Retention, 5.0) The fork of the retractor is located under the housing.

Note: The persuader (015.7068 Persuader) is provided to further rod reduction.

Step 2

The Set Screws are loaded onto the Hex Driver with Handle, 5.0 and loosely inserted into each housing. Do not final tighten the set screw with the Hex Driver.

Compression and Distraction

Step 1

Once the rod is placed, compression and distraction can be accomplished utilizing the Compressor (015.7091 Compressor) and the Distractor (015.7092 Distractor).

Step 2

The Derotator (015.7068 Rod Derotator) is used to firmly grasp the rod rotation or to establish a purchase point for distraction or compression if necessary.

Final Tightening

Step 1

Use the T-Handle, Torque Limiting, 1/4" Square QC (12 N-m) (100.2023 T-Handle, Torque Limiting, 1/4" Square QC (12 N-m)) with Hex Driver, 1/4" Square QC, Self-Retention, 5.0 for final locking of the set screw.

Step 2

Place the T-handle, Torque Limiting with the Hex Driver through the Anti-Torque Device (015.7071 Anti-Torque Device, D5.5mm Rod)

Step 3

Turn handle clockwise until an audible click is heard.

INSTRUCTIONS FOR USE

SYMBOL TRANSLATION

Catalog Number

Lot Number

Quantity

Non-Sterile

Single Use Only

See Package Insert for Labeling Limitation

Federal Law (USA) restricts this device to sale, distribution, or use by or on the order of a physician

Manufacturer

Date of Manufacture

eIFU indicator

CE Mark is applicable for only the following systems:
SEURAT™ Universal Pedicle Screw System
RAPHAEL™ Pedicle Screw System
PICASSO™ MIS Spinal System

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NOTES

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