

HARRIER[®] SA

3D Printed Titanium Standalone ALIF

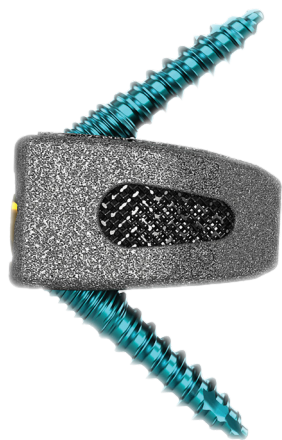




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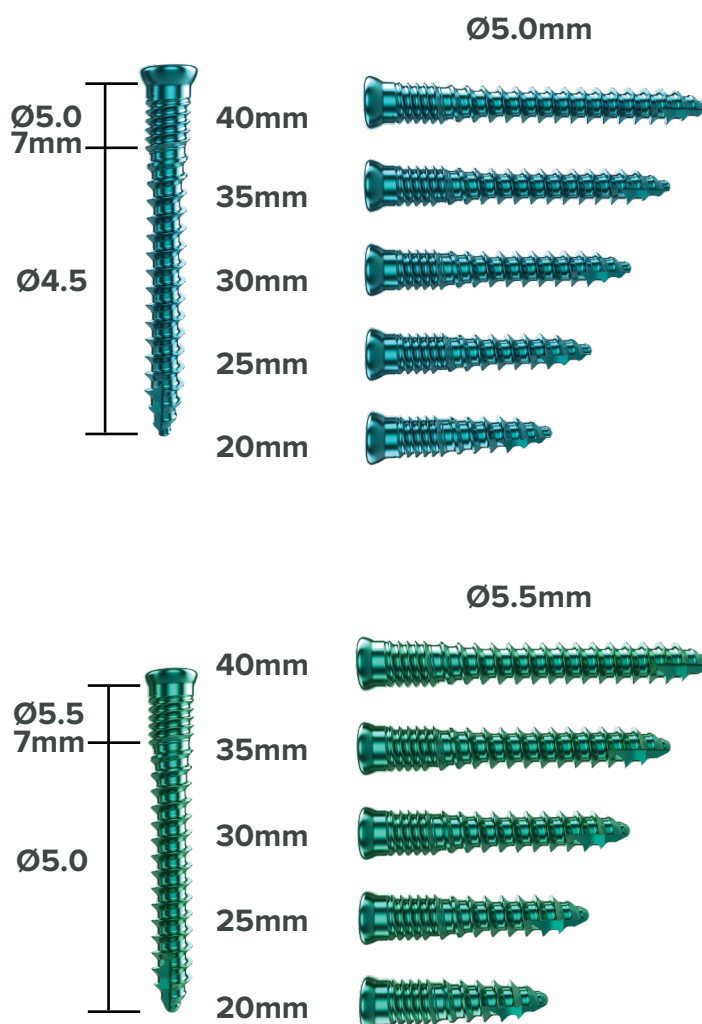
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Introduction

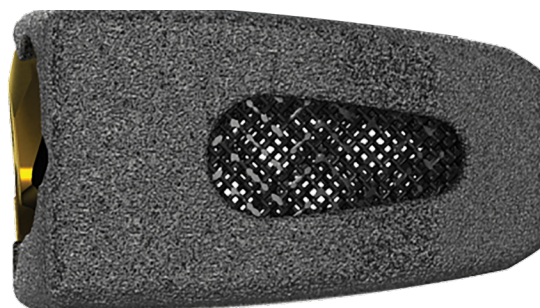
Harrier® SA is a standalone, screw-based system made of 3D-printed titanium. It incorporates ChoiceSpine's proprietary BioBond® Porous Trabecular Structure and is designed for Anterior Lumbar Interbody Fusion (ALIF). The system features four titanium, dual-threaded corticocancellous screws for lag purchase. The interbody comes in three anatomical footprints with multiple lordotic options and large graft windows. Harrier SA includes an integrated cam-locking mechanism for visual and tactile locking confirmation. It is intended for standalone use, but it can also be used with ChoiceSpine's Raven® Anterior Lumbar Plate System for additional fixation if required.

Screw Offerings

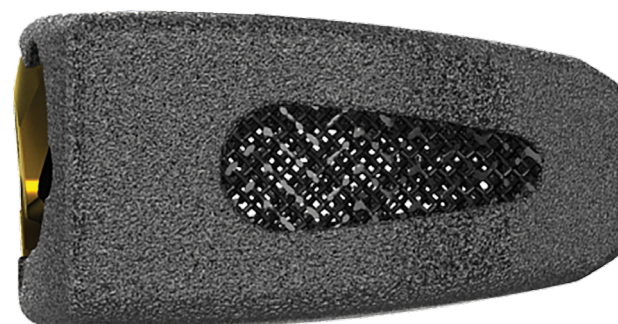


Interbody Overview

FOOTPRINT	LORDOSIS	ANTERIOR HEIGHT (mm)	POSTERIOR HEIGHT (mm)	GRAFT VOLUME (cc)
26mm X 32mm	10°	12.0	8.3	2.8
		13.5	9.9	3.4
		15.0	11.4	3.9
		17.0	13.4	4.6
		19.0	15.4	5.3
	15°	12.0	6.6	2.5
		13.5	8.1	3.0
		15.0	9.6	3.5
		17.0	11.6	4.2
		19.0	13.6	4.9
	20°	15.0	7.3	3.0
		17.0	9.3	3.7
		19.0	11.3	4.4



FOOTPRINT	LORDOSIS	ANTERIOR HEIGHT (mm)	POSTERIOR HEIGHT (mm)	GRAFT VOLUME (cc)
28mm X 36mm	10°	12.0	8.3	3.8
		13.5	9.8	4.5
		15.0	11.3	5.2
		17.0	13.3	6.2
		19.0	15.3	7.1
	15°	12.0	6.5	3.3
		13.5	8.0	4.0
		15.0	9.5	4.7
		17.0	11.5	5.7
		19.0	13.5	6.7
	20°	15.0	7.2	4.0
		17.0	9.2	5.0
		19.0	11.2	5.9



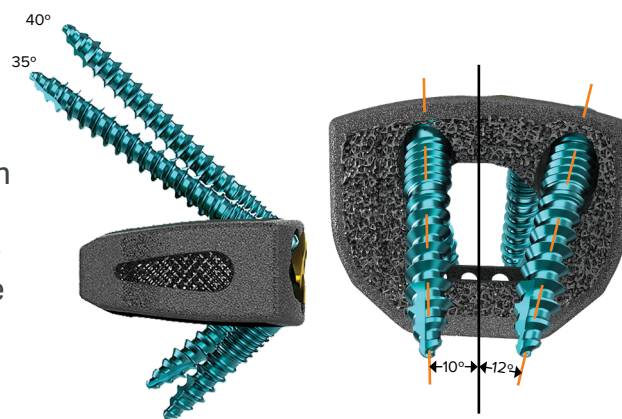
FOOTPRINT	LORDOSIS	ANTERIOR HEIGHT (mm)	POSTERIOR HEIGHT (mm)	GRAFT VOLUME (cc)
30mm X 40mm	10°	12.0	8.2	5.0
		13.5	9.6	5.9
		15.0	11.2	6.9
		17.0	13.2	8.1
		19.0	15.2	9.4
	15°	12.0	6.4	4.3
		13.5	7.9	5.3
		15.0	9.4	6.2
		17.0	11.4	7.5
		19.0	13.3	8.8
	20°	15.0	6.9	5.4
		17.0	9.1	6.6
		19.0	11.1	7.9



NOTE: 20 degrees requires additional fixation.

Screw Positioning

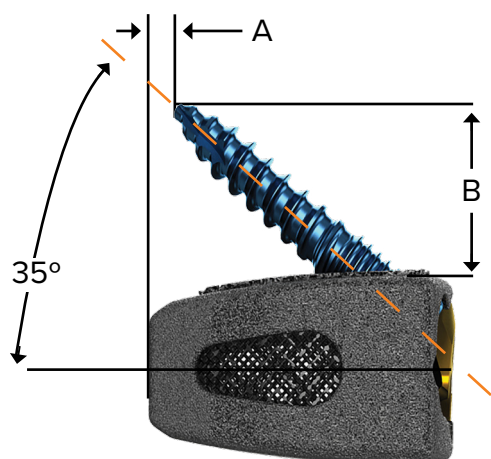
Screw trajectory should be considered when selecting an appropriate screw length and diameter. As shown in the figures to the right, the neutral angle of the screws in the cranial/caudal direction is 40°. The neutral angle of the lateral screws is 12° medial and 10° medial for the interior screws. The Ø5.0 Screws allow 5° of angulation in all directions from the neutral axis.



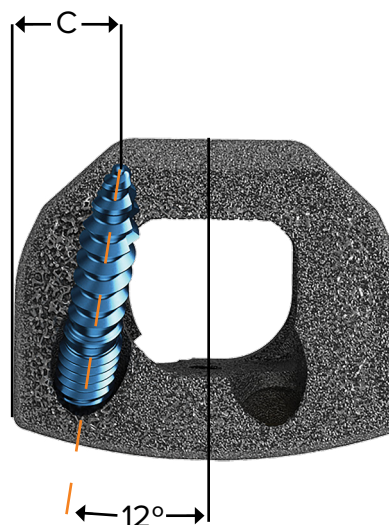
The figures below indicate the location of the screw tip relative to the interbody when positioned at the lowest cranial/caudal angle (35°) and neutral medial angle (12°). This angle positions the screw tip the furthest posterior. (Refer to the charts below for positional locations for each screw length.)

"A" refers to the measurement of the screw tip from the posterior edge of the Interbody. "B" refers to the vertical measurement from the tallest cranial/caudal face of the interbody. Lastly, "C" refers to the measurement from the lateral edge of the Interbody to the screw tip.

26mm x 32mm Footprint



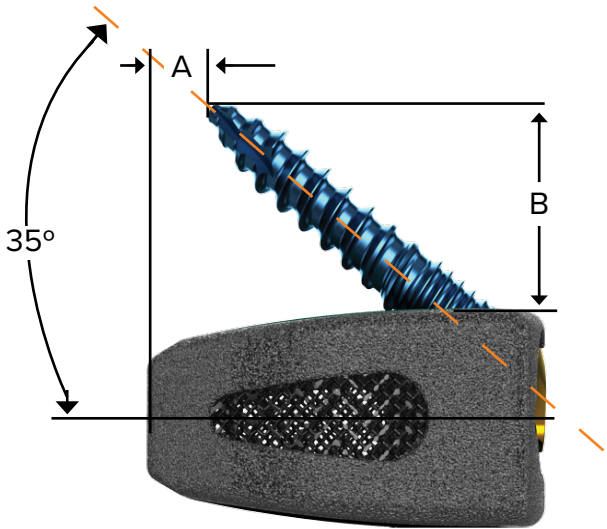
NOTE: Shown with Ø5.0mm x 25mm Screw



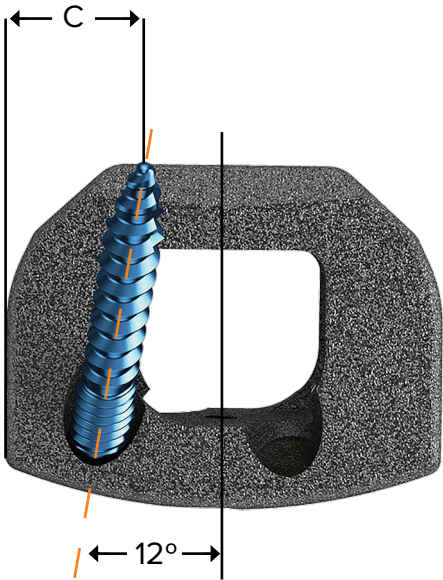
26mm x 32mm Footprint				
Screw Ø (mm)	Screw Length (mm)	A(mm)	B(mm)	C(mm)
5.0mm	20mm	-4.8mm	8.8mm	8.9mm
5.0mm	25mm	-0.8mm	11.7mm	9.7mm
5.0mm	30mm	3.2mm	14.6mm	10.6mm
5.0mm	35mm	7.2mm	17.4mm	11.4mm
5.0mm	40mm	11.2mm	20.3mm	12.3mm

NOTE: The highlighted row in the chart illustrates the above implant shown.

28mm x 36mm Footprint



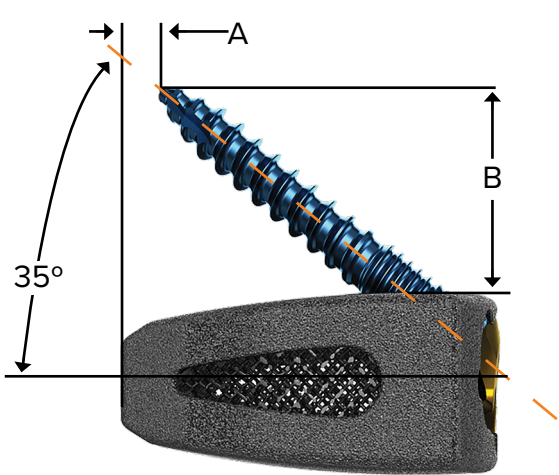
NOTE: Shown with Ø5.0mm x 25mm Screw



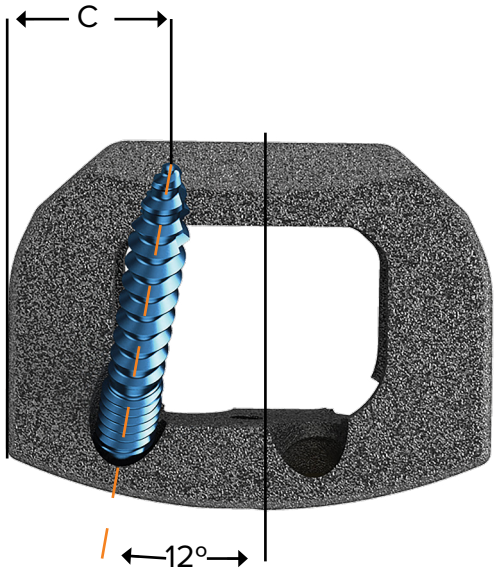
28mm x 36mm Footprint				
Screw Ø (mm)	Screw Length (mm)	A(mm)	B(mm)	C(mm)
5.0mm	20mm	-6.8mm	8.8mm	10.9mm
5.0mm	25mm	-2.8mm	11.7mm	11.7mm
5.0mm	30mm	1.2mm	14.6mm	12.6mm
5.0mm	35mm	5.2mm	17.4mm	13.4mm
5.0mm	40mm	9.2mm	20.3mm	14.3mm

NOTE: The highlighted row in the chart illustrates the above implant shown.

30mm x40mm Footprint



NOTE: Shown with Ø5.0mm x 30mm Screw



30mm x 40mm Footprint				
Screw Ø (mm)	Screw Length (mm)	A(mm)	B(mm)	C(mm)
5.0mm	20mm	-8.8mm	8.8mm	12.9mm
5.0mm	25mm	-4.8mm	11.7mm	13.7mm
5.0mm	30mm	-0.82mm	14.6mm	14.6mm
5.0mm	35mm	3.2mm	17.4mm	15.4mm
5.0mm	40mm	7.2mm	20.3mm	16.3mm

NOTE: The highlighted row in the chart illustrates the above implant shown.

Preoperative Preparation

- Review and inspect all instrumentation and implants prior to sterilization.
- Replace or add any necessary components for the planned surgery.
- Surgeon must be fully experienced with the required spinal fusion techniques.
- Read the Instructions for Use (IFU) for a product description and a list of warnings, cautions, contraindications, and risks.

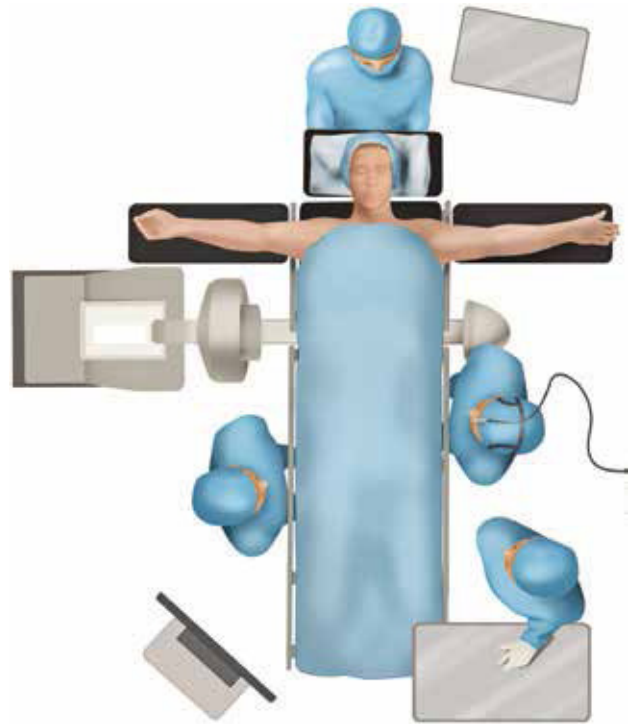


Figure 1

Surgical Exposure and Site Preparation

- Position and drape the patient in the supine position (Figure 1).
- Expose the affected levels via a standard incision and tissue dissection.
- Perform any necessary bone and tissue removal.
- Prepare vertebral endplates via the use of the provided disc preparation instrumentation to remove disc material and end plate cartilage (Figure 2).
- Load the selected **Bullet Distractor (Y070-XXXX10XXB)** onto the **Bullet Distractor Inserter (Y070-0060)** with the **Small Quick-Connect Handle (Y070-0042)** via the thread feature on the **Bullet Distractor**.
- Insert the **Bullet Distractor** into the disc space lateral to the midline. Utilize a **Mallet (Y070-0036)** if needed. A second **Bullet Distractor** of the same height is available if distraction on the opposite side is needed.
- Remove and reinsert **Bullet Distractors** of sequential heights to distract and prepare the disc space. Also, the **Slap Hammer (V070-0004)** can be attached to the **Small Quick-Connect Handle** if required to remove the **Bullet Distractor**.



Figure 2

NOTE: Avoid rotating the handle of the **Bullet Distractor Inserter** during **Bullet Distractor** insertion or removal. The **Trial Inserter (Y070-0002)** may be used to insert the **Bullet Distractor** if rotational control of the **Bullet Distractor** is needed.

Bullet Distractor Dimensions

PART NUMBER	HEIGHT(mm)	WIDTH(mm)	LENGTH(mm)	LORDOSIS
Y070-24061008B	8	6	24	10°
Y070-24071009B	9	7		
Y070-24081010B	10	8		
Y070-24091011B	11	9		
Y070-24101012B	12	10		
Y070-24111013B	13	10		
Y070-24121014B	14	10		
Y070-24131015B	15	10		



Preparation and Trials

- After disc preparation is complete, prepare vertebral endplates by removing superficial cartilaginous layers. Preserve the posterior and lateral walls of the annulus for peripheral support.
- Attach the Small Quick-Connect Handle (Y070-0042) to the Trial Inserter (Y070-0002).
- Select the appropriate size Trial (Y070-XXXX10XXC) (Figure 3a) from the Trial Caddy (Y090-1200) and assemble the Trial onto the Trial Inserter by aligning the Trial to the inserter (Figure 3b) and rotating the knob clockwise to secure the Trial (Figure 4). Ensure the Trial is connected securely.



Figure 3a



Figure 3b

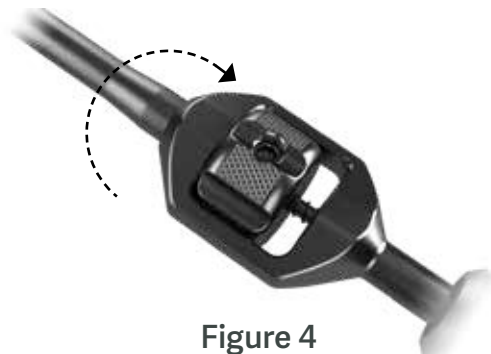


Figure 4

NOTE: If attachment of the Trial Inserter to the Trial is difficult, rotate the knob of the Trial Inserter a half turn counter-clockwise and then clockwise for thread alignment.

- Insert the Trial into the disc space (Figure 5). In order to maintain disc height and ensure segment stabilization, select a Trial height that provides a secure fit in the targeted disc space (Figure 6). Use fluoroscopic guidance for confirmation. Start with the smallest height progressing to taller heights until the desired fit is achieved.



Figure 5



Figure 6

Harrier SA Implantation

- Select the **Cage Inserter (Y070-0045)** and attach to the **Small Quick-Connect Handle**.
- Align the Implant to the **Cage Inserter** and tighten threaded knob (Figure 7). Ensure the implant is connected securely.
- The bone graft can be packed into the Interbody. See page 5 for graft volume reference.



Figure 7

- Insert the interbody into the disc space (Figure 8).
- Radiographically confirm the position and placement.



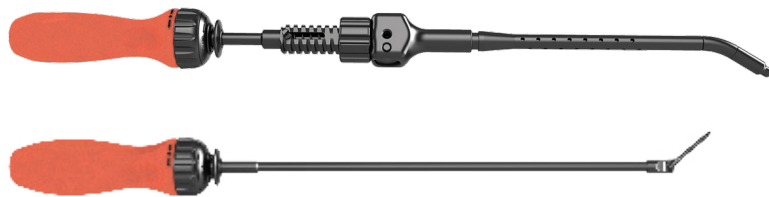
Figure 8

Screw Hole Preparation

The Harrier® SA Standalone ALIF System offers a variety of Instruments for screw hole preparation.

- Attach the Ratcheting Handle (M070-0003) to the selected Instruments.
- Apply axial force to the handle until the awl tip pierces the bone (Figure 9).

NOTE: The Retractable Awl (Y070-0039) has variable depth up to 20mm. The Straight Awl (Y070-0006) has a depth of 15mm.



NOTE: The U-Joint Variable Angle Awl (Y070-0026) and the U-Joint Variable Angle Drill (Y070-0014) are **ONLY** to be used with the Guide (Y070-0003); both have a depth of 15mm.



Figure 9



Screw Insertion

The Harrier® SA Standalone ALIF System offers Straight, Fixed, and Variable Angle Screwdrivers for screw insertion.

- Depending on the angle and position of the Interbody, select the desired Driver and attach the Ratcheting Handle (M070-0003) to the proximal end of the instrument.
- Based on fluoroscopic guidance, select the desired screw length and load the Screw (YT35-5XXX) from the Screw Caddy with the Screwdriver.
- Drive the Screw until it is fully seated.
- There is an Angled Finishing Driver (Y070-0064) and a Straight Finishing Driver (Y070-0063) to help advance the screw for final seating if necessary.

NOTE: The finishing drivers are solid tip and will not retain the screws.

NOTE: Screws should be flush with the anterior face of the implant.

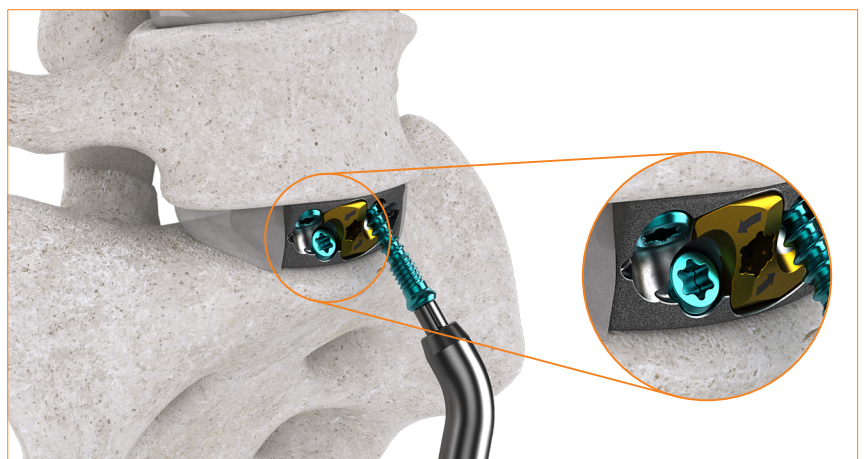


Figure 10

Cam Locking Mechanism

The Cam Locking Mechanism should be engaged after final seating of all Screws.

- To lock cam take the **Cam Driver (Y070-0054)** and attach it to the **Torque Handle (2TS4-18-C06)**. Engage the **Cam Driver** to the cam hexalobe at the center of the interbody. Rotate the cam 35 degrees until engagement of the cam is in the locked position. Once the cam is in the locked position it is both felt and seen.

NOTE: If you hear the torque click over and the cam is not fully locked, this indicates the screws are proud and must be fully seated in order for final cam lock to occur. The torque handle is 18 in-lbs.

- Cam locking engagement is demonstrated below:



NOTE: Make sure to turn Cam lock counterclockwise. Do not over rotate.

Removing the Harrier SA Implant (if necessary)

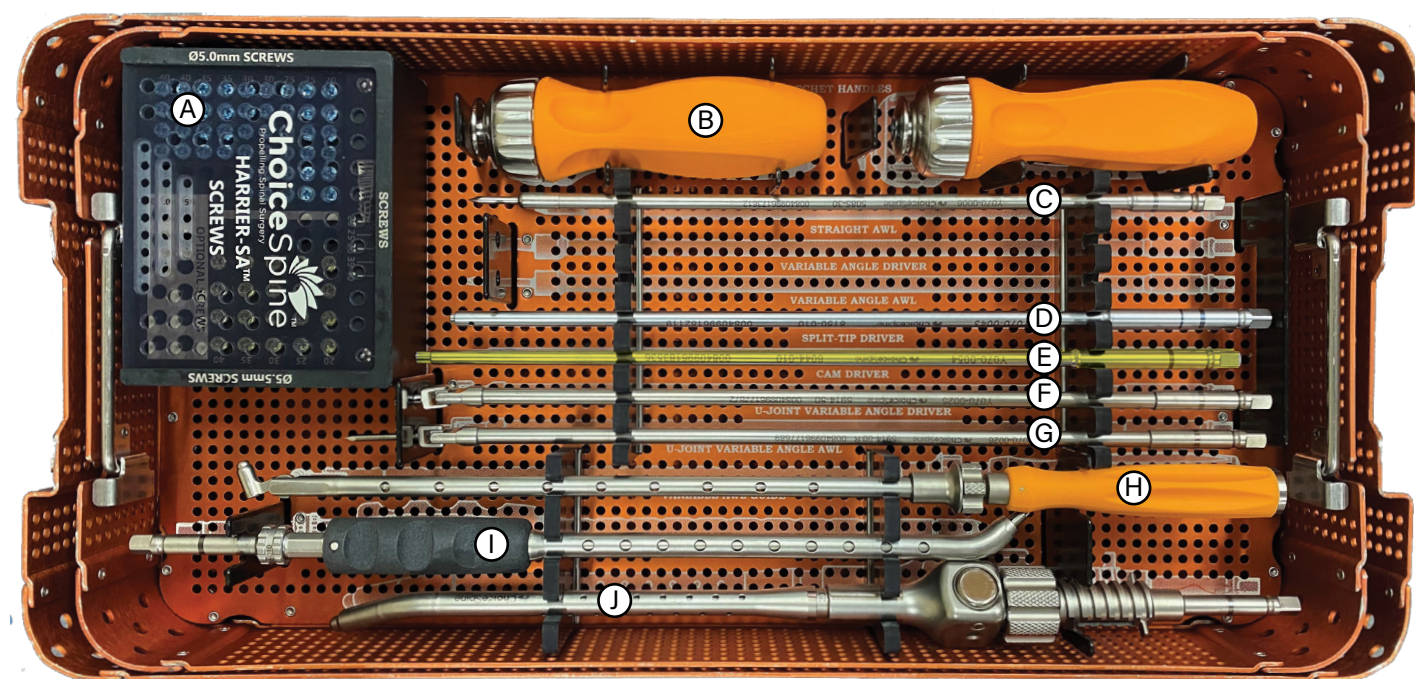
- Unlock the cam mechanism by engaging the **Cam Driver** with the cam hexalobe and turn clockwise to unlock.
- Remove all screws using the **Straight or Angled Screwdriver**.
- Attach the **Cage Inserter (with the Small Quick- Connect Handle)** to the Interbody.
- Attach the **Slap Hammer (V070-0004)** to the handle and impact until the Interbody is removed from the disc space.



Disassembly Instructions for Fixed Angle Driver (Y070-0044) & Retractable Awl (Y070-0039)

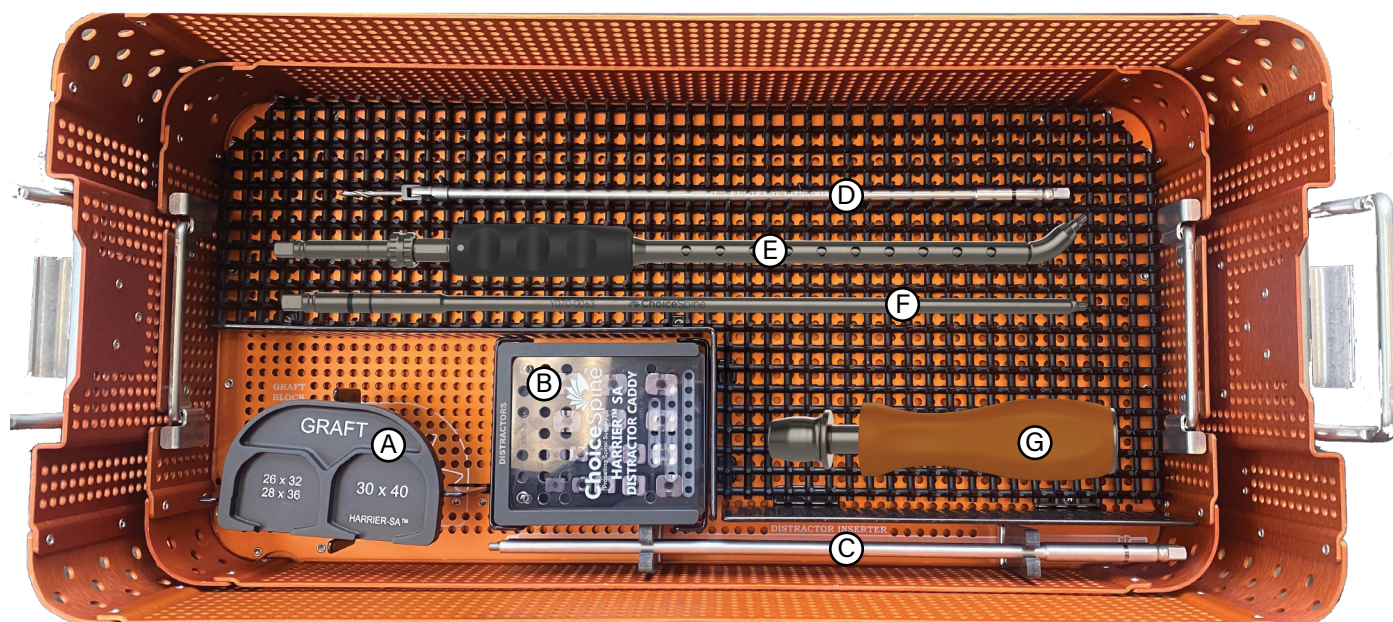
After use, disassemble the Fixed Angled Driver (Y070-0044) & Retractable Awl (Y070-0039) for cleaning. It is recommended to clean components disassembled.

Harrier® SA Instrument Top Tray



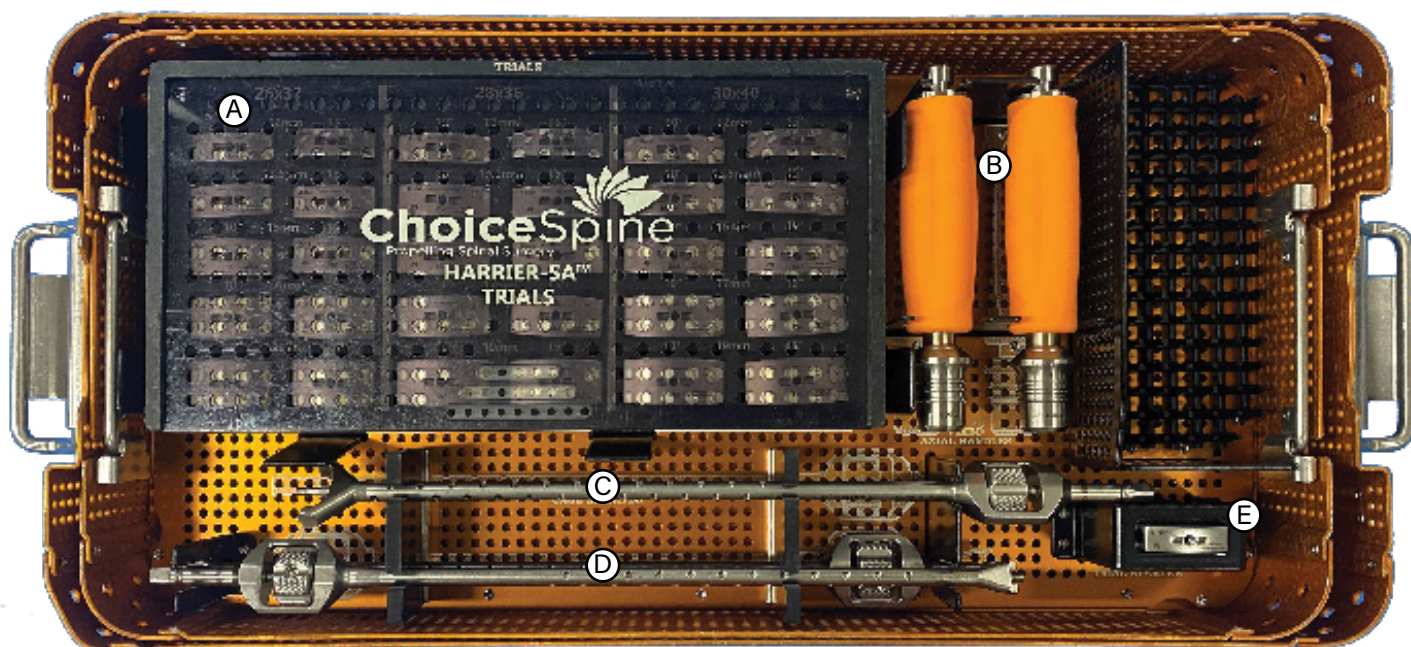
- | | |
|--|---|
| (A) Screw Caddy (5.0 & 5.5MM, 20-40MM – 5MM Incr.) Y090-1100 | (F) U-Joint Variable Angle Driver Y070-0025 |
| (B) Axial Ratchet Handles (x2) M070-0003 | (G) U-Joint Variable Angle Awl Y070-0026 |
| (C) Straight Awl Y070-0006 | (H) Variable Awl Guide Y070-0003 |
| (D) Split- Tip Driver Y070-0043 | (I) Fixed Angle Driver Y070-0044 |
| (E) Cam Driver Y070-0054 | (J) Retractable Awl Y070-0039 |

Harrier® SA Instrument Bottom Tray



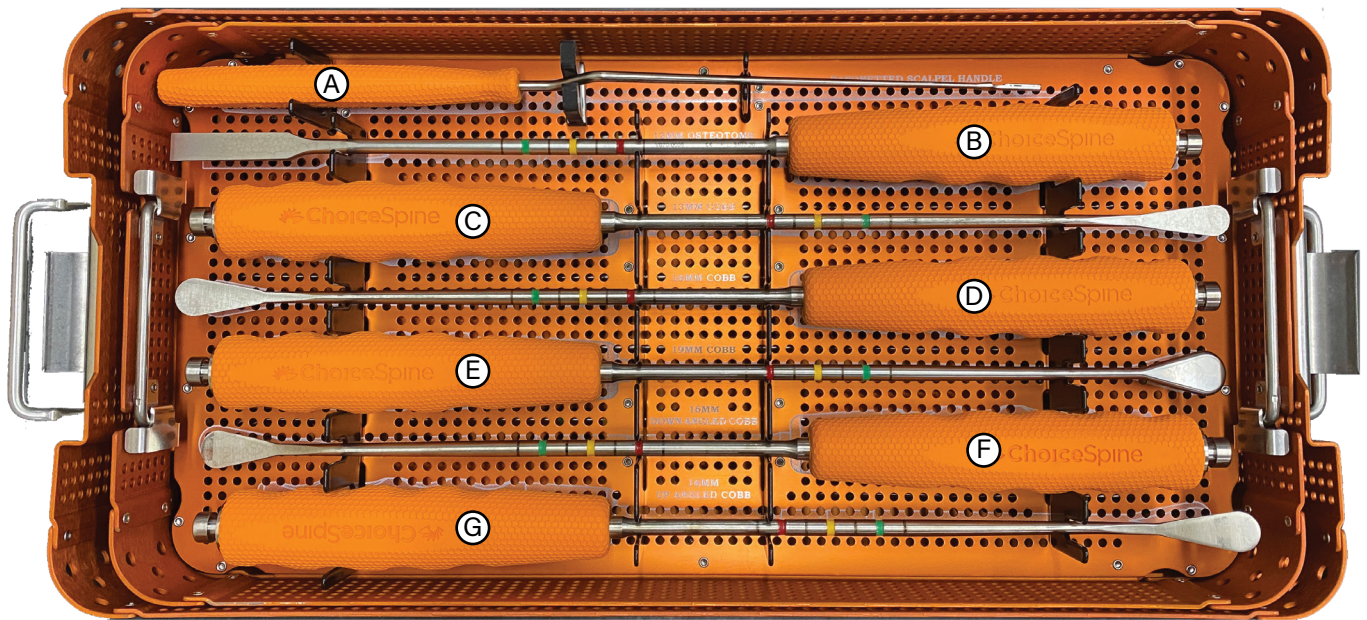
- Ⓐ Graft Block Y070-0037
- Ⓑ Distractor Caddy Y090-1600
- Ⓒ Distractor Inserter (x2) Y070-0060
- Ⓓ U-Joint Variable Angle Drill Y070-0014
- Ⓔ Angled Finishing Driver Y070-0064
- Ⓕ Straight Finishing Driver Y070-0063
- Ⓖ Torque Handle 2TS4-18-C06

Harrier® SA Trial Tray



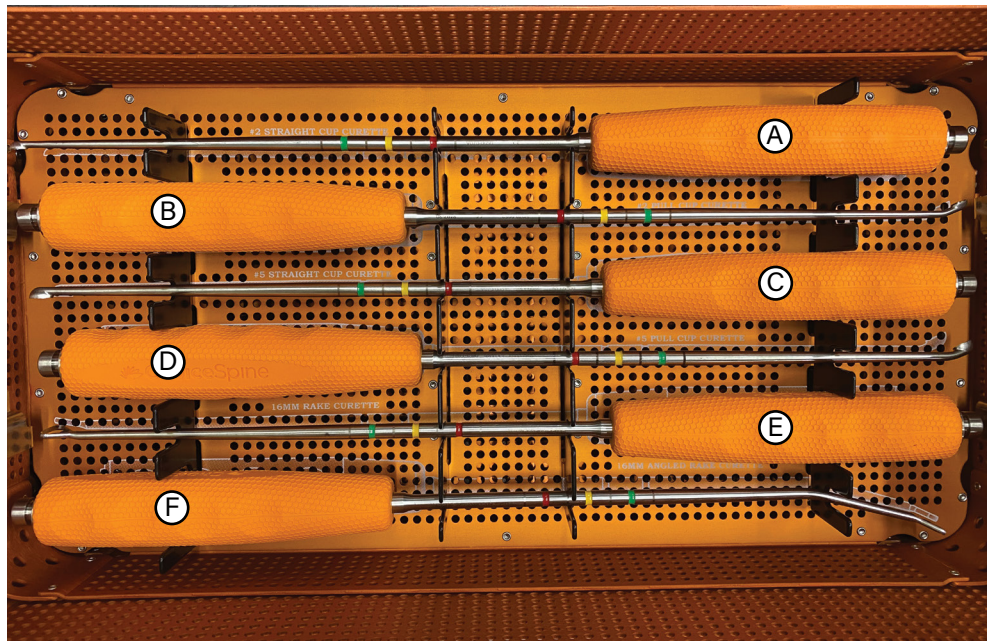
- Ⓐ Trial Caddy Y090-1200
- Ⓑ Small Quick-Connect Handle (x2) Y070-0042
- Ⓒ Cage Inserter Y070-0045
- Ⓓ Trial Inserter (x2) Y070-0002
- Ⓔ Trial Starter Y070-0040

Harrier® SA Disc Prep Top Tray (ALDP Case # 1)



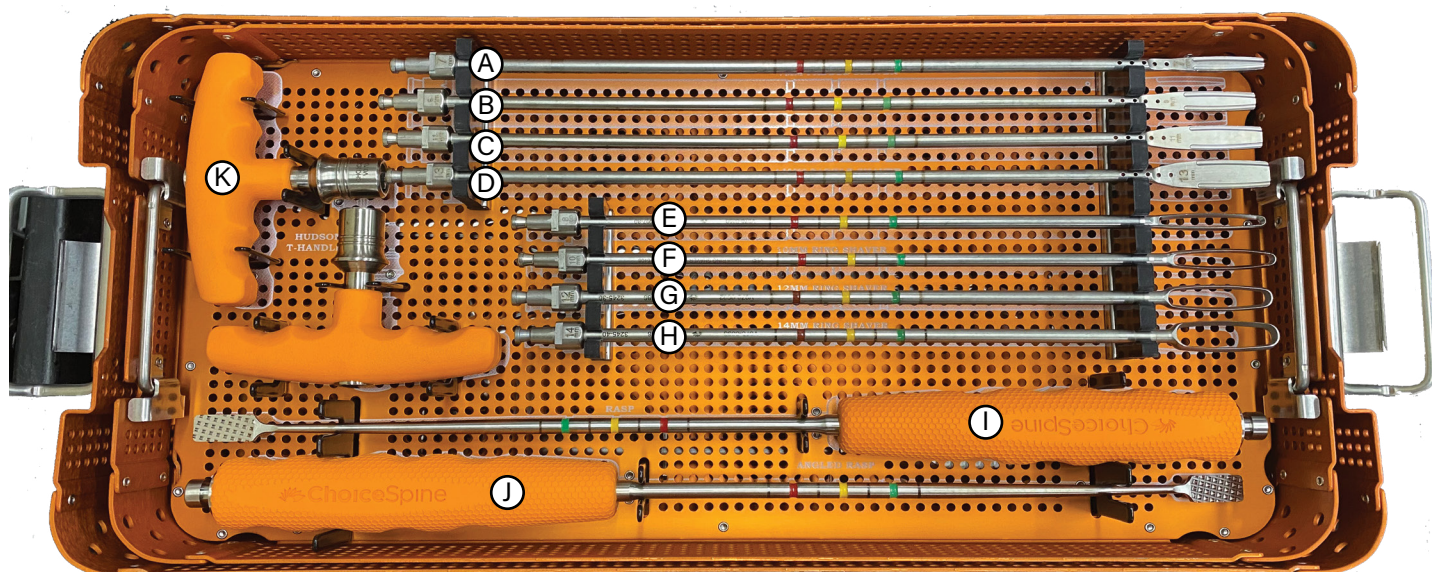
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|--------------------------------------|------------------------------------|
| Ⓐ Bayoneted Scalpel Holder V090-0035 | Ⓔ 19mm Cobb V070-0022 |
| Ⓑ 12mm Osteotome V070-0005 | Ⓕ 16mm Cobb, Angled Down V070-0024 |
| Ⓒ 13mm Cobb V070-0020 | Ⓖ 16mm Cobb, Angled Up V070-0027 |
| Ⓓ 16mm Cobb V070-0021 | |

Harrier® SA Disc Prep Bottom Tray (ALDP Case # 1)



- | | |
|--------------------------------------|---------------------------------------|
| Ⓐ Cup Curette, #2 Straight V070-0050 | Ⓓ Cup Curette, #5 Pull V070-0053 |
| Ⓑ Cup Curette, #2 Pull V070-0052 | Ⓔ Rake Curette, 16mm V070-0011 |
| Ⓒ Cup Curette, #5 Straight V070-0051 | Ⓕ Angled Rake Curette, 16mm V070-0013 |

Harrier® SA Disc Prep Top Tray (ALDP Case # 2)



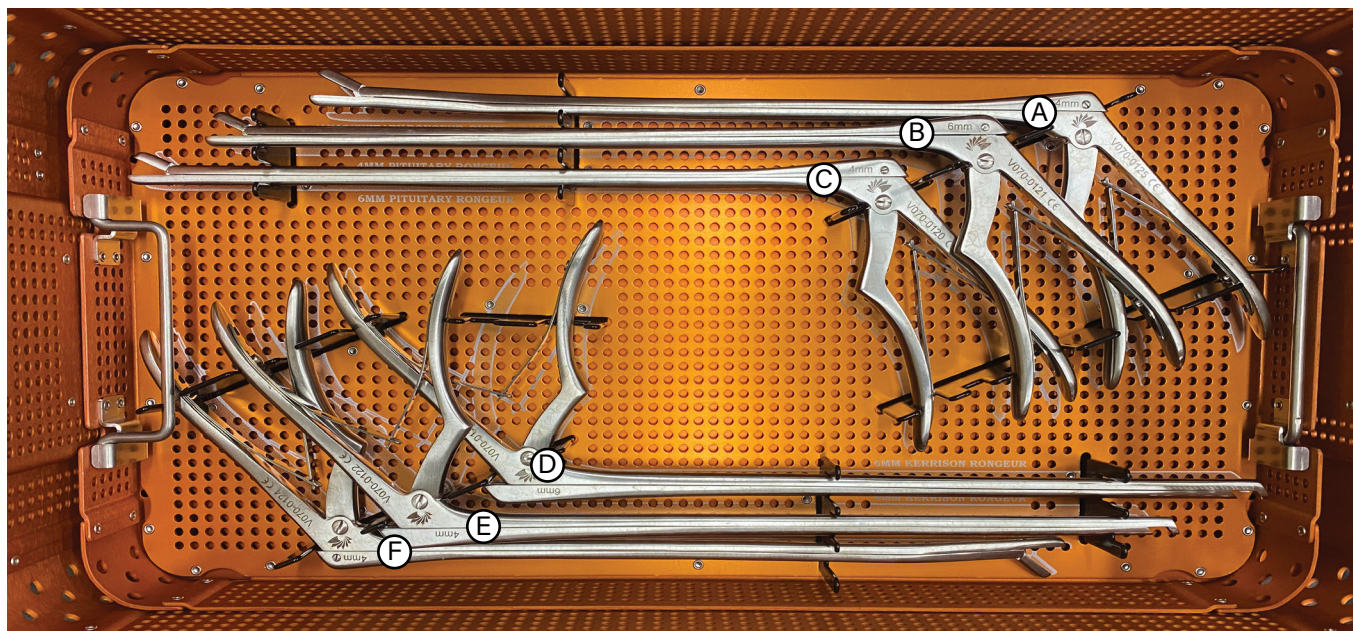
- | | | |
|---------------------------------|------------------------------|---------------------------|
| Ⓐ Paddle Shaver, 7mm V070-0101 | Ⓔ Ring Saver, 8mm V070-0090 | Ⓛ Rasp V070-0040 |
| Ⓑ Paddle Shaver, 9mm V070-0103 | Ⓛ Ring Saver, 10mm V070-0091 | Ⓜ Angled Rasp V070-0041 |
| Ⓒ Paddle Shaver, 11mm V070-0105 | Ⓛ Ring Saver, 12mm V070-0092 | Ⓨ T-Handle (x2) V070-0100 |
| Ⓓ Paddle Shaver, 13mm V070-0107 | Ⓛ Ring Saver, 14mm V070-0093 | |

Harrier® SA Disc Prep Middle Tray (ALDP Case # 2)



- | | | |
|--------------------|------------------------------------|-------------------------|
| Ⓐ Mallet Y070-0036 | Ⓑ Rongeur, Double Action Y070-0035 | Ⓒ Slap Hammer V070-0004 |
|--------------------|------------------------------------|-------------------------|

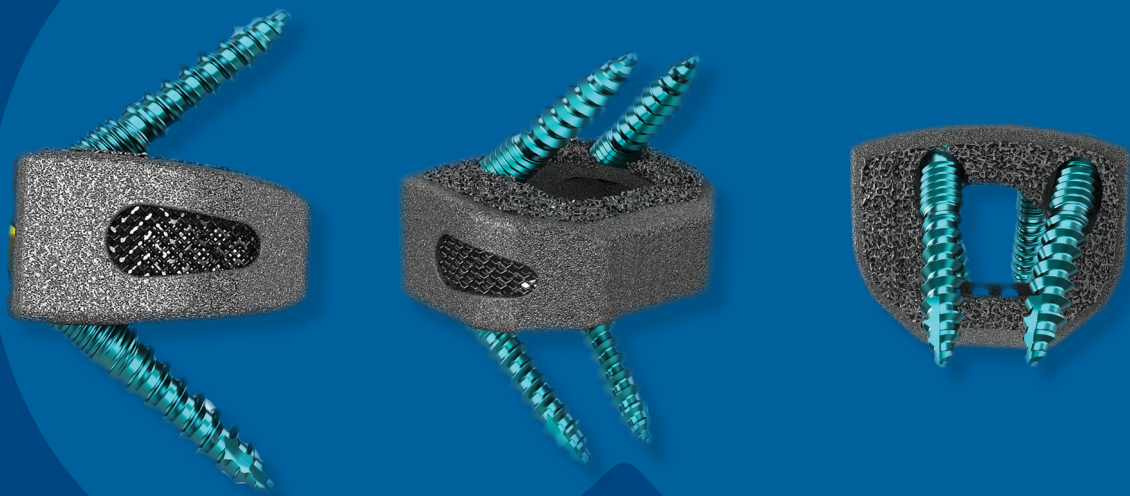
Harrier® SA Disc Prep Bottom Tray (ALDP Case # 2)



- Ⓐ 4mm Pituitary Rongeur, Right Angled V070-0124
- Ⓑ 4mm Pituitary Rongeur V070-0120
- Ⓒ 6mm Pituitary Rongeur V070-0121
- Ⓓ 6mm Kerrison Rongeur V070-0123
- Ⓔ 4mm Kerrison Rongeur V070-0122
- Ⓕ 4mm Pituitary Rongeur, Left Angled V070-0125

Notes:

For Instructions for Use please visit <https://choicespine-eifu.com/>



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Spine the Right Way.SM



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