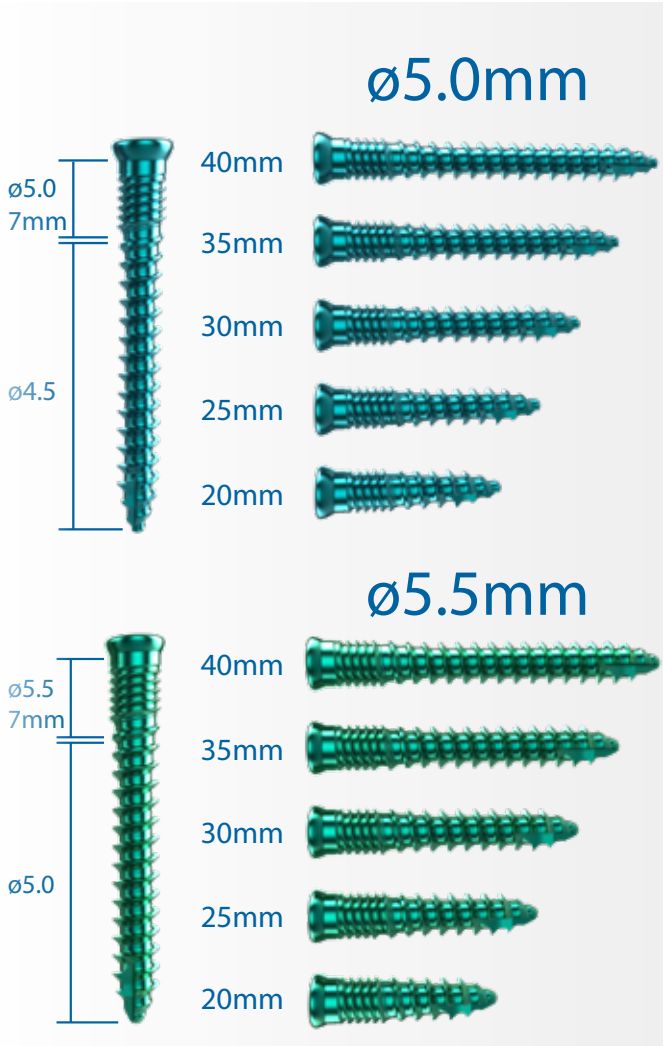
ChoiceSpine™
Propelling Spinal Surgery

HARRIER™ SA Surgical Technique

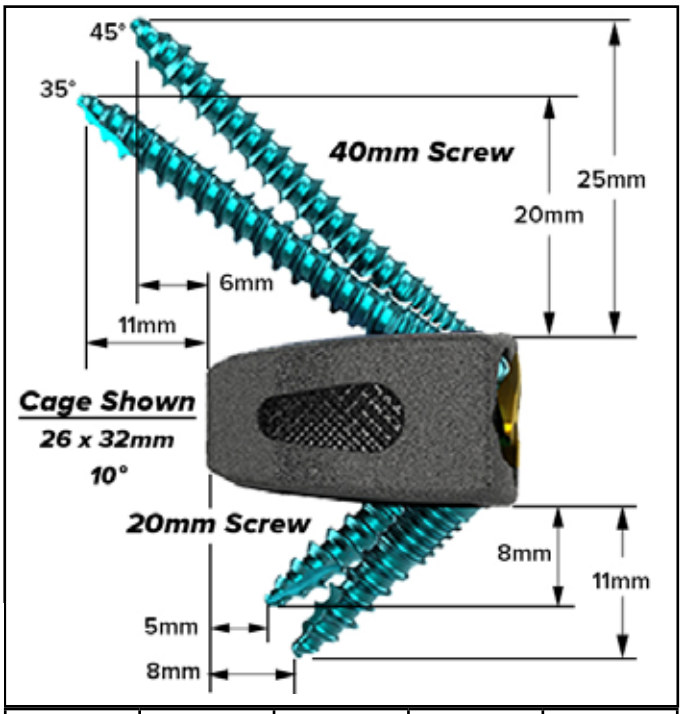
Stand Alone Anterior Spacer System

Introduction

Harrier SA is a comprehensive stand alone system designed for Anterior Lumbar Interbody Fusion (ALIF). Featuring BioBond™ 3D printed titanium porous structure, Harrier SA is available in 3 anatomical footprints with large graft volume windows. The Harrier SA system features 4 individual titanium, dual-threaded corticocancellous screws designed for lag purchase and graft loading. For added security, an integrated cam locking mechanism allows for quick and secure back-out prevention. The Harrier SA system includes multiple insertion options for minimally disruptive and seamless access to the anterior lumbar spine.

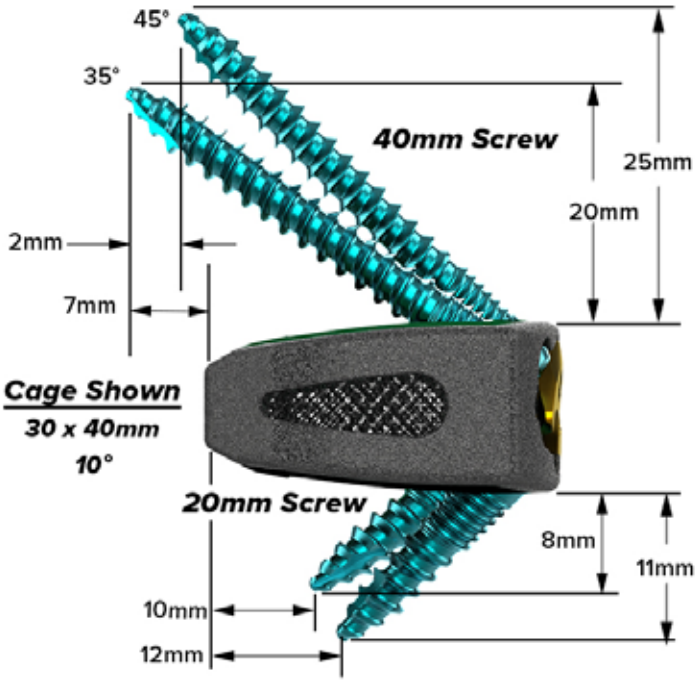


FOOTPRINT	LORDOSIS	ANTERIOR HEIGHT (mm)	POSTERIOR HEIGHT (mm)	GRAFT VOLUME (cc)
26 x 32	10°	12.0	8.1	2.8
		13.5	9.6	3.4
		15.0	11.1	3.9
		17.0	13.1	4.6
		19.0	15.1	5.3
	15°	12.0	6.1	2.5
		13.5	7.6	3.0
		15.0	9.1	3.5
		17.0	11.1	4.2
		19.0	13.1	4.9



FOOTPRINT	LORDOSIS	ANTERIOR HEIGHT (mm)	POSTERIOR HEIGHT (mm)	GRAFT VOLUME (cc)
28 x 36	10°	12.0	7.7	3.8
		13.5	9.2	4.5
		15.0	10.7	5.2
		17.0	12.7	6.2
		19.0	14.7	7.1
	15°	12.0	5.6	3.3
		13.5	7.1	4.0
		15.0	8.6	4.7
		17.0	10.6	5.7
		19.0	12.6	6.7

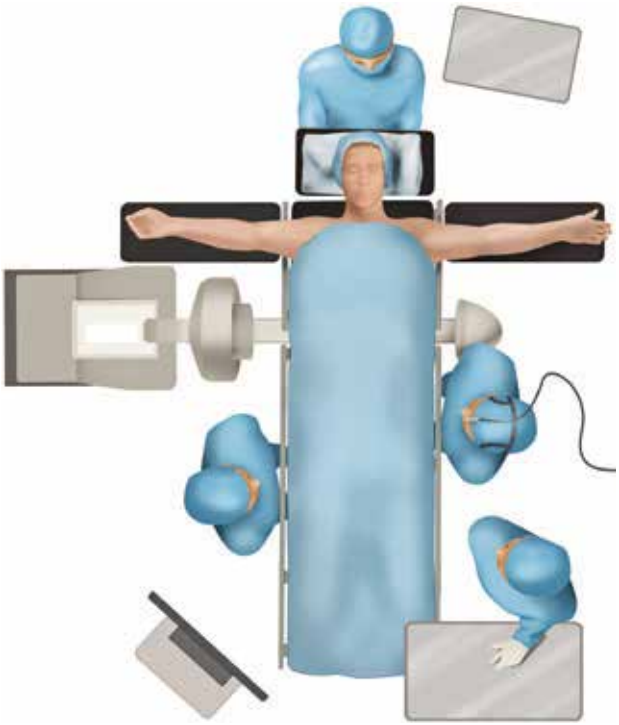
FOOTPRINT	LORDOSIS	ANTERIOR HEIGHT (mm)	POSTERIOR HEIGHT (mm)	GRAFT VOLUME (cc)
30 x 40	10°	12.0	7.4	5.0
		13.5	8.9	5.9
		15.0	10.4	6.9
		17.0	12.4	8.1
		19.0	14.4	9.4
	15°	12.0	5.1	4.3
		13.5	6.6	5.3
		15.0	8.1	6.2
		17.0	10.1	7.5
		19.0	12.1	8.8



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 Harrier SA Disc Prep set (Y090-2000) to remove disc material and endplate cartilage (Figure 2).

Figure 2

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.

• After preparing the intervertebral disc space, the trials are inserted to determine the size of the desired implant.

• Attach the Fixed Axial Handle (Y070-0030) to the Trial Inserter (Y070-0002).

• Select the appropriate size trial (Figure 3a) from the Trial Caddy 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 4a). Ensure the trial is connected securely (Figure 4b).

Figure 3a

Figure 3b

Figure 4a

Figure 4b

Preparation and Trials Cont.

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 (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

Once the appropriate implant size has been selected, bone graft can be packed into the implant. Then, select the Cage Inserter (Y070-0045) and attach to the Fixed Axial Handle (Y070-0042). Align the implant to the cage inserter and tighten threaded knob (Figure 7). Ensure the implant is connected securely.

Figure 7

Insert the implant into the disc space (Figure 8). Radiographically confirm the position and placement of the implant.

Figure 8

Screw Hole Preparation

The Harrier SA stand alone ALIF system offers a variety of awls for screw hole preparation. Attach the fixed axial handle (Y070-0042) to the selected awl. 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) and Fixed Angle Awl (Y070-0004) have a constant depth of 15mm.

Note: The Variable Angle Awls (Y070-0015 and Y070-0026) are ONLY to be used with the Awl Guide (Y070-0003).

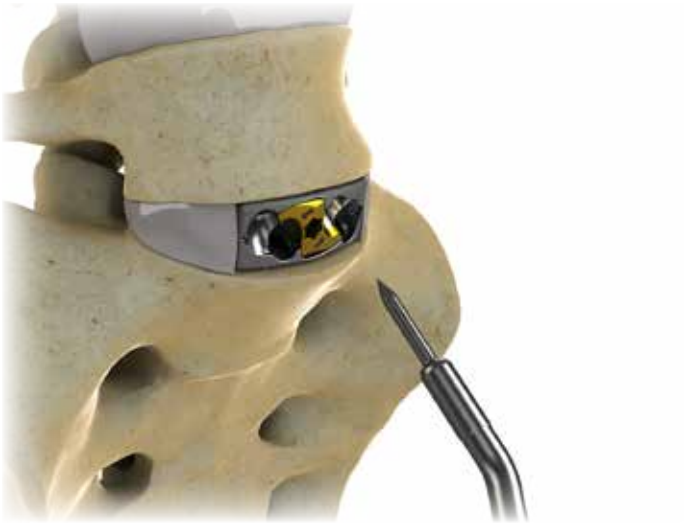
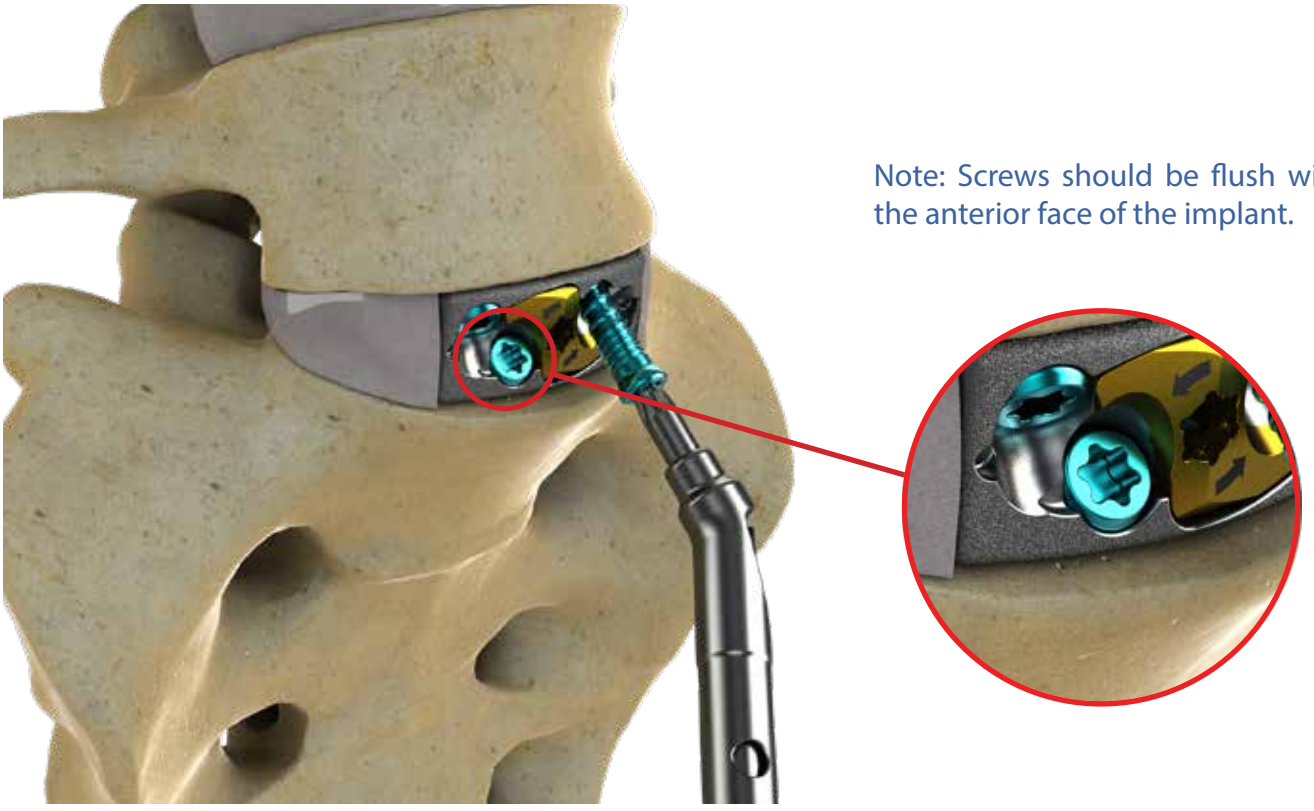


Figure 9

Screw Insertion

The Harrier SA stand alone ALIF system offers straight, fixed, and variable angle screwdrivers for screw insertion. Depending on the angle and position of the implant, 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 "stab and grab" the screw from the screw caddy with the screwdriver. All Harrier SA screwdrivers are designed to be self retaining. Insert the screw through the implant into the prepared hole. Drive the screw until it is fully seated.

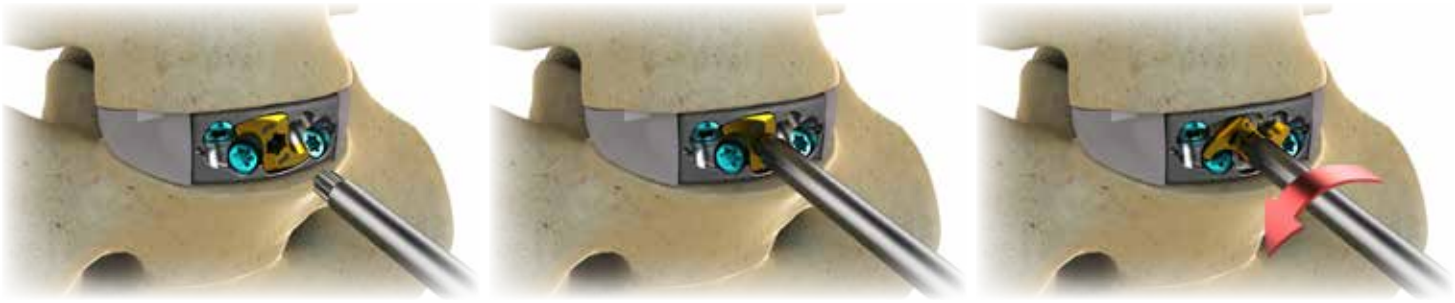


Note: Screws should be flush with the anterior face of the implant.

Figure 10

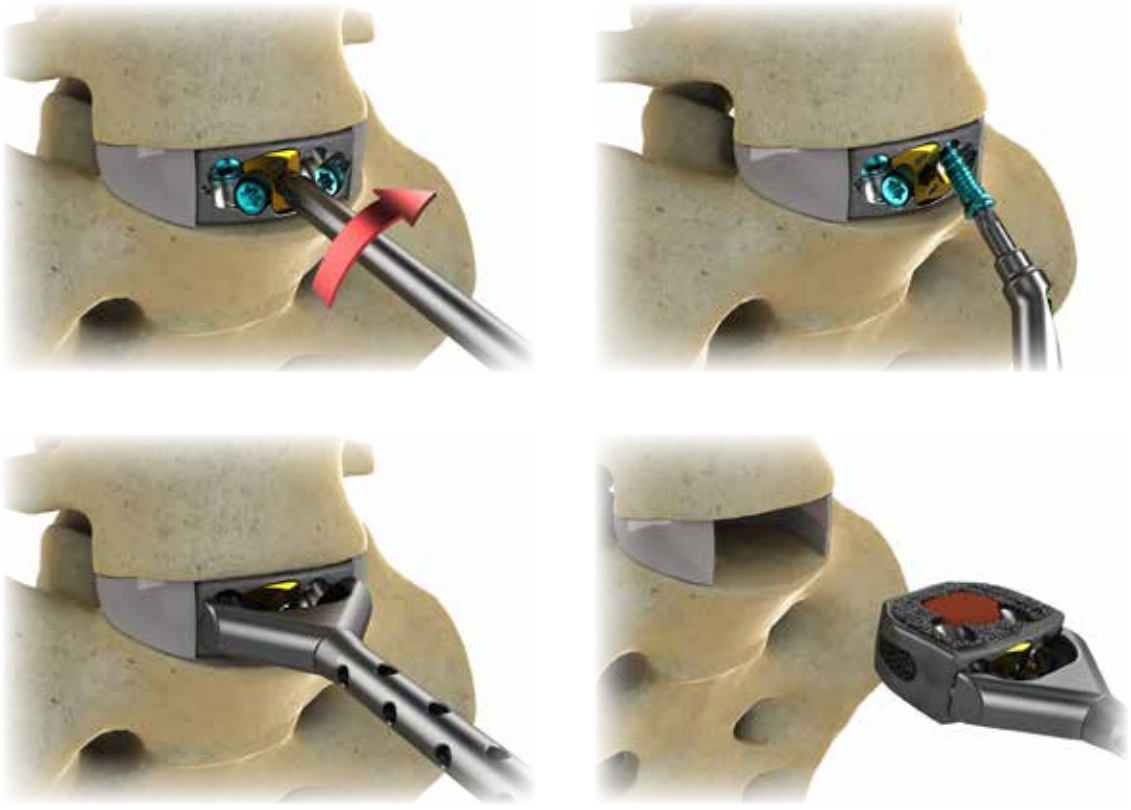
Cam Lock Mechanism

The cam locking mechanism should be engaged after placement of all screws. To engage, insert the T27 hexalobe driver (Y070-0054) at the center of the implant. Rotate the cam counterclockwise until engagement of the cam in the locked position is both felt and seen. Cam locking engagement is demonstrated below:



Removing the Harrier SA implant (if necessary)

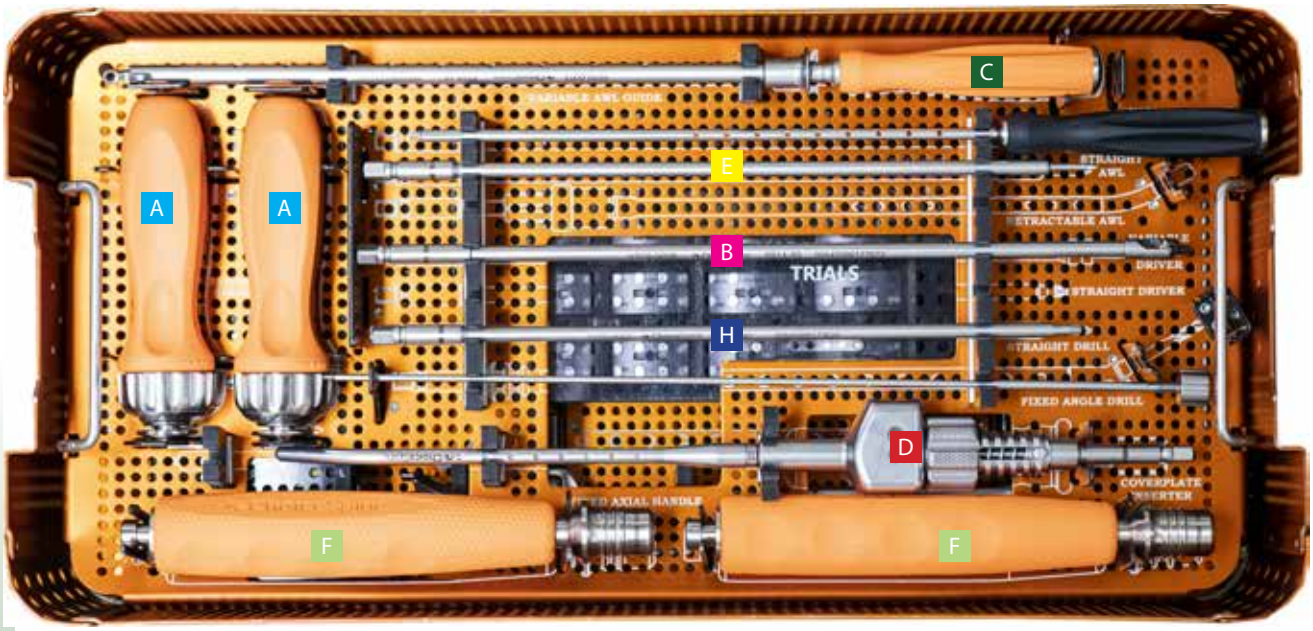
- Unlock the cam mechanism by turning the T27 hexalobe clockwise.
- Remove all screws using the straight or angled screwdriver.
- Attach the cage inserter to the implant.
- Attach the slap hammer to the handle and impact until the implant is removed from the disc space.



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 Ratchet Axial Handle

B Variable Angle Awl

C Awl Guide

D Retractable Awl

E Straight Awl

F Fixed Axial Handle

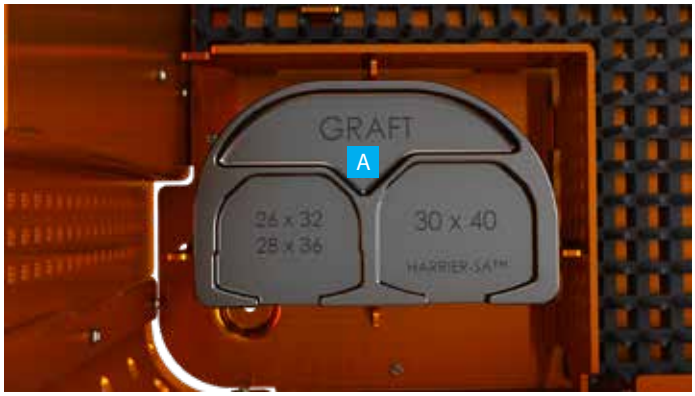
H Straight Driver

Harrier SA Instrument Middle Tray

A Screw Caddy

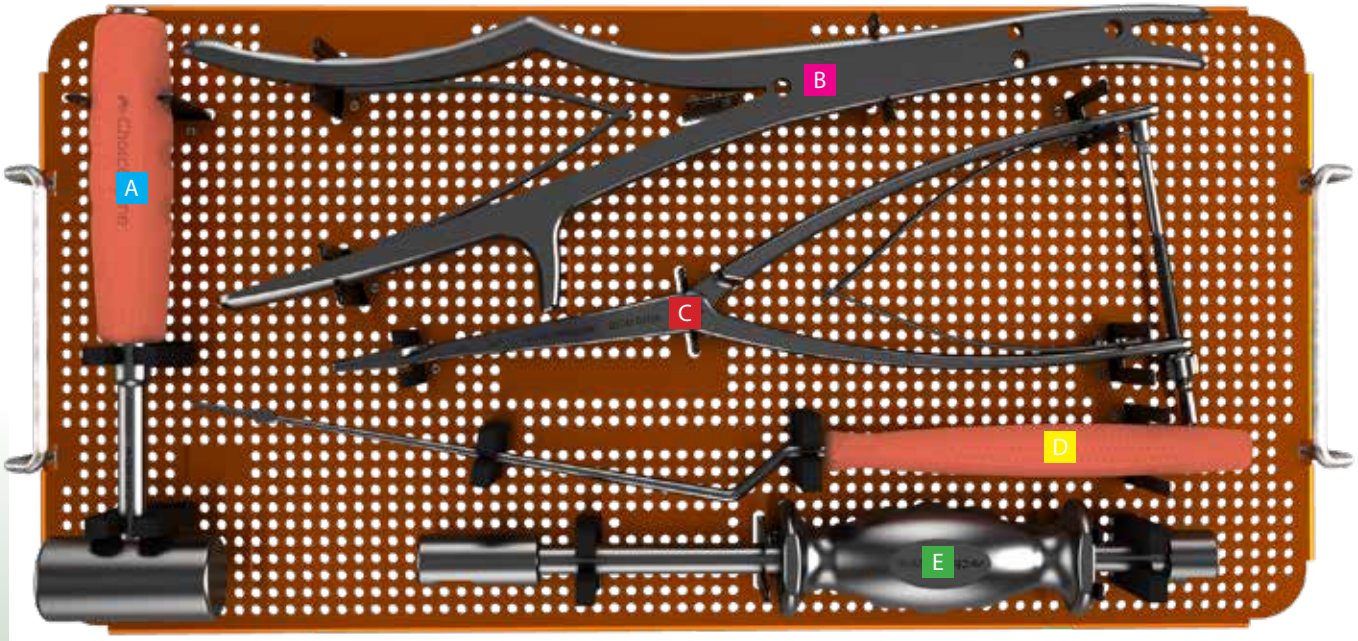
B Fixed Angle Inserter

Harrier SA Instrument Bottom Tray



A Graft Block

Harrier SA Disc Prep Top Tray



A Mallet

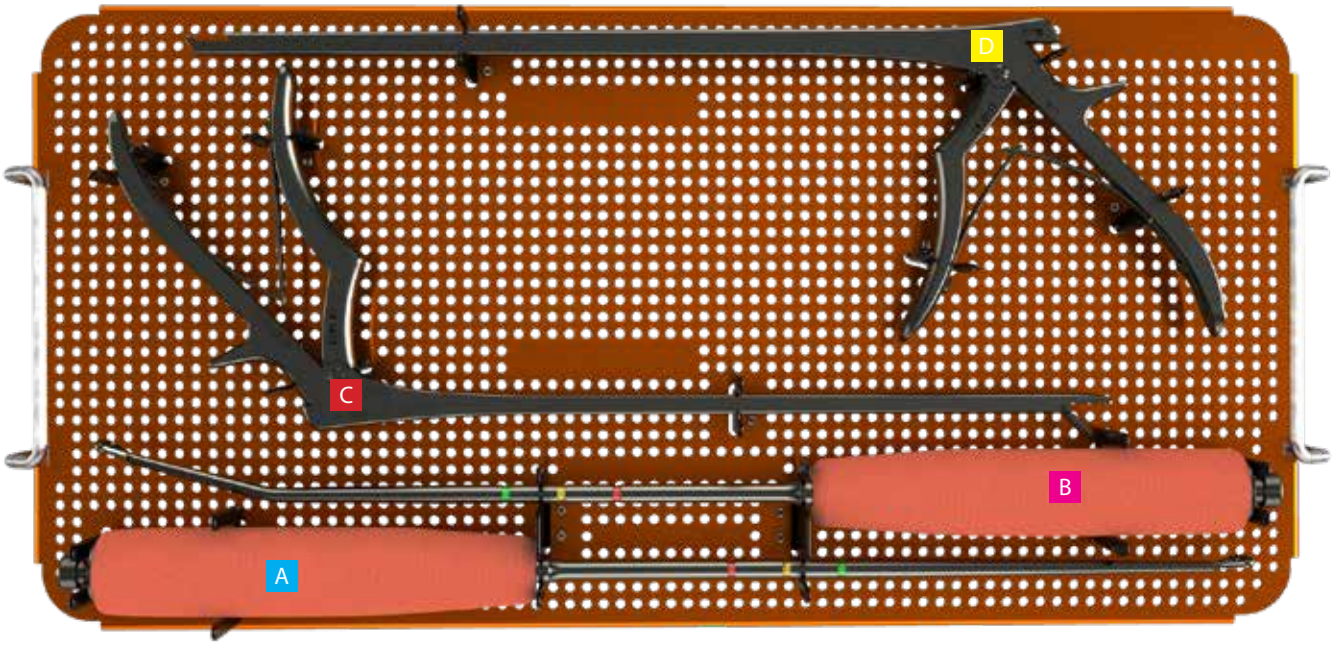
B Double Action Rongeur

C Spreader

D Bayoneted Scalpel Handle

E Slap Hammer

Harrier SA Disc Prep Middle Tray

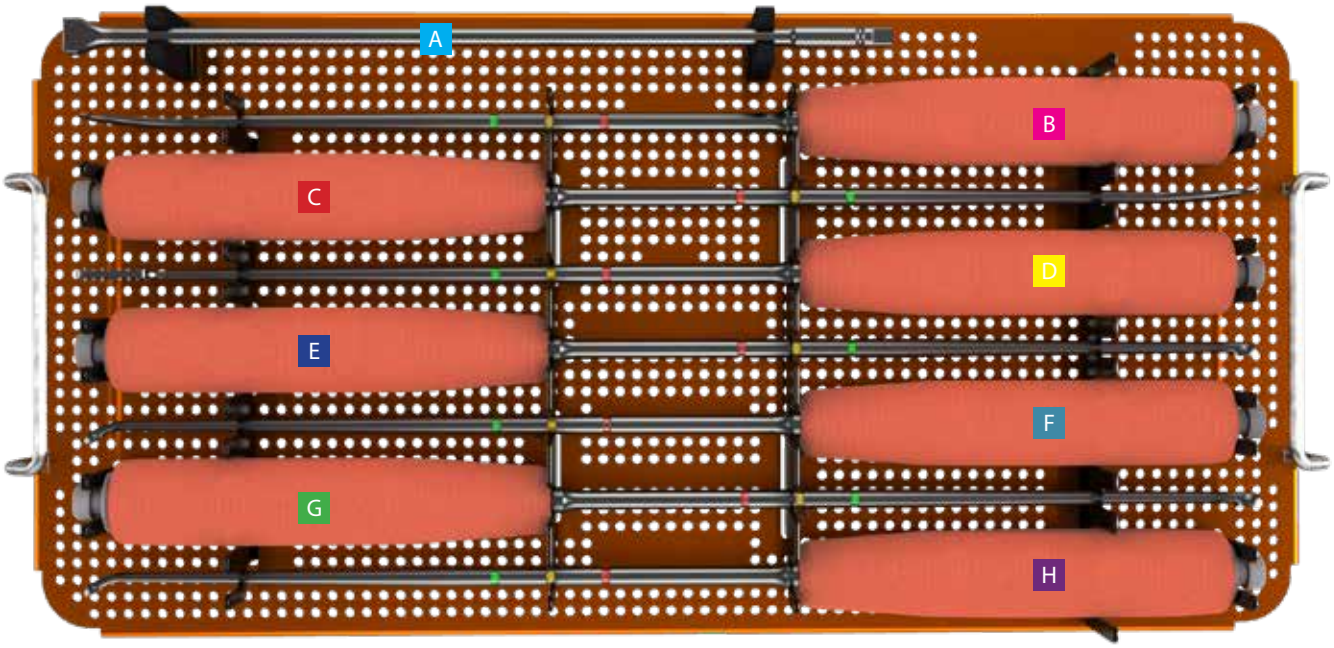


A 16mm Rake Curette

B 16mm Angled Rake Curette

C 4mm and 6mm Pituitary Rongeur (Stacked)

D 4mm and 6mm Kerrison Rongeur (Stacked)



A Cage Tamp

B 13mm Cobb

C 19mm Cobb

D Rasp

E #2 Straight Cup Curette

F #2 Pull Cup Curette

G #5 Straight Cup Curette

H #5 Pull Cup Curette

Description:
The Choice Spine HARRIER-SA Lumbar Interbody System is available in various sizes to accommodate individual patient anatomy. The Choice Spine HARRIER-SA Lumbar Interbody System is a stand-alone device intended to be used with (4) bone screws.

The implant spacer components are made from multiple materials: Invibio PEEK OPTIMA™ HA Enhanced with Tantalum markers per ASTM F560 or Ti-6Al-4V ELI Titanium per ASTM F3001, Class C. Plates, cover plates, and screws are made from Ti-6Al-4V ELI Titanium per ASTM F136.

Indications for Use:
The Choice Spine HARRIER-SA Lumbar Interbody System is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. This device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. This device is designed to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

The Choice Spine HARRIER-SA Lumbar Interbody System is a stand-alone device intended to be used with four bone screws. Supplemental fixation, cleared by the FDA for use in the lumbosacral spine, must be used with spacers ≥20°. Supplemental fixation must also be used whenever fewer than four bone screws are used.

Contraindications:
Contraindications include, but are not limited to:
- Infection, systemic or localized
- Signs of local inflammation
- Morbid obesity
- Fever or leukocytosis
- Mental illness
- Alcoholism or drug abuse
- Pregnancy
- Severe osteopenia
- Suspected or documented sensitivity allergies to the implant materials
- Presence of congenital abnormalities, vague spinal anatomy, tumors, or any other condition which prevents secure implant screw fixation and/or decreases the useful life of the device
- Any condition having inadequate tissue coverage over the operative site
- Any circumstances not described under Indications for Use
- Patients unwilling or unable to follow post- operative instructions
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis (osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft)

Cautions:
- If the packaging of the sterile packed implants is compromised, the sterility of the device will be compromised and the implant must be discarded.
- If the expiry date on the packaging has been exceeded, the implant must be discarded.
- Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium components must NOT be used together.
- Do not use components of the Harrier-SA Lumbar Interbody System with components from any other system.
- As with all orthopedic implants, none of the Harrier-SA Lumbar Interbody System implants should ever be reused under any circumstances.

Precautions:
- Patients who smoke have been shown to have an increased incidence of non-union. These patients should be advised of this fact and warned of the consequences. Other poor candidates for spine fusion include obese, malnourished, those with poor muscle and bone quality, and nerve paralysis patients.
- The implantation of spinal systems should be performed only by spinal surgeons fully experienced in the surgical techniques required for the use of such implants. Even with the use of spinal implants, a successful result in terms of pain, function, or fusion is not always achieved in every surgical case. The physician should consider patient weight and patient activity.

Warnings:
- Patient compliance to postoperative pre-cautions will greatly affect surgical outcomes.
- The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. All implants should be examined before use and discarded if damaged.
- The Harrier-SA Lumbar Interbody System spacers with lordotic angles greater than or equal to 20 degrees are required to be used with supplemental fixation to reduce the risk of implant expulsion.
- The Harrier-SA Lumbar Interbody System has not been evaluated for safety and compatibility in MR environment. It has not been tested for heating and migration in the MR environment. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

Possible Adverse Effects:
Pre-operatively, the patient should be made aware of the following possible adverse effects of spinal implant surgery. Additional surgery may be necessary to correct some of these effects:
- Early or late loosening of the components
- Disassembly, bending, loosening, and/or breakage
- Foreign body reaction to the implants including possible tumor migration
- Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site which may result in skin breakdown and/or wound complications
- Pressure on the skin from components where there is inadequate tissue coverage over the implant
- Loss of proper spinal curvature, correction, height, and/or reduction
- Infection
- Hemorrhage of blood vessels and/or hematomas
- Bone graft, intervertebral body and/or sacral fracture at, above, and/or below the level of surgery
- Non-union or delayed union
- Loss of neurological function (e.g., bowel or bladder dysfunction), appearance of radiculopathy, and/or development of pain
- Gastrointestinal and/or reproductive system compromise, including sterility
- Cessation of growth of the fused portion of the spine
- Death
- Neurovascular compromise including paralysis or other types of serious injuries

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