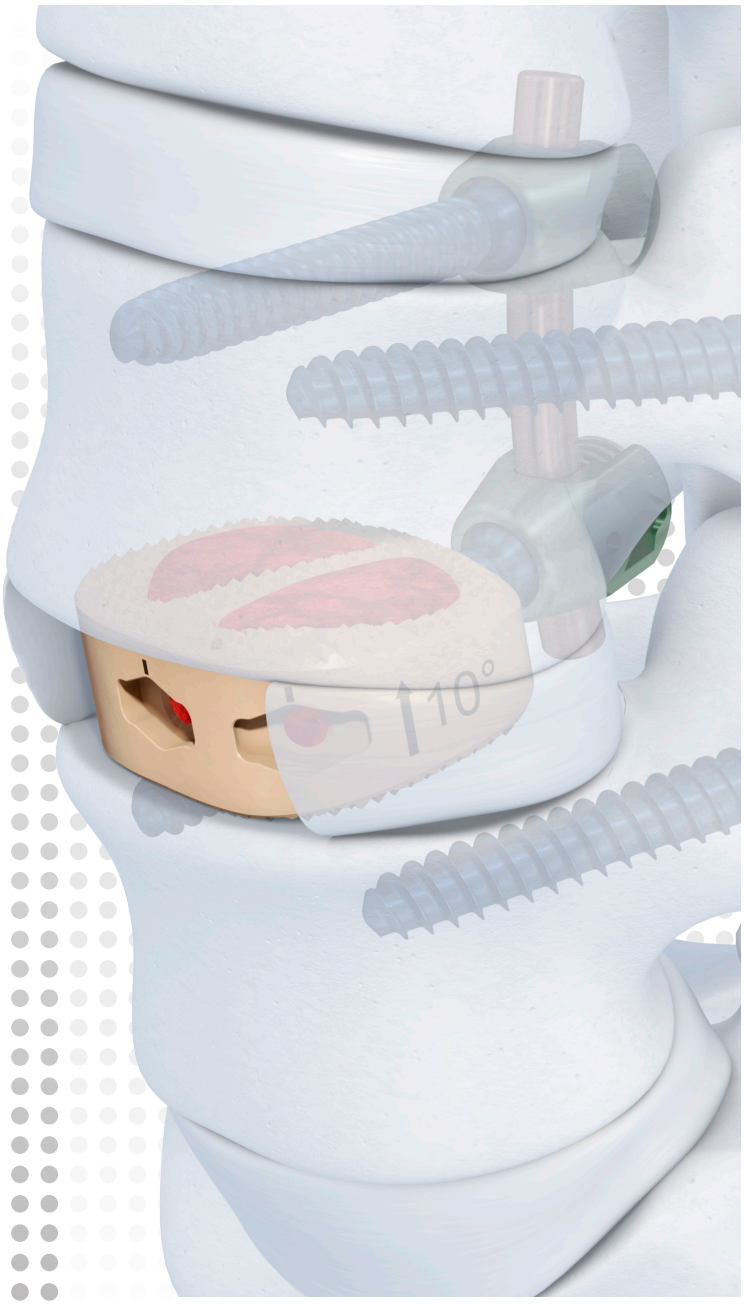
SYNCAGE™ Evolution Spacer System

Surgical Technique



DePuy Synthes
THE ORTHOPAEDICS COMPANY OF Johnson & Johnson

Image intensifier control

▲ Warnings & Precautions

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Processing, Reprocessing, Care and Maintenance

For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:

http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

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* For Product Catalog contact your local DePuy Synthes representative

SYNCAGE™ Evolution Spacer System

Implant Overview

Pyramidal teeth

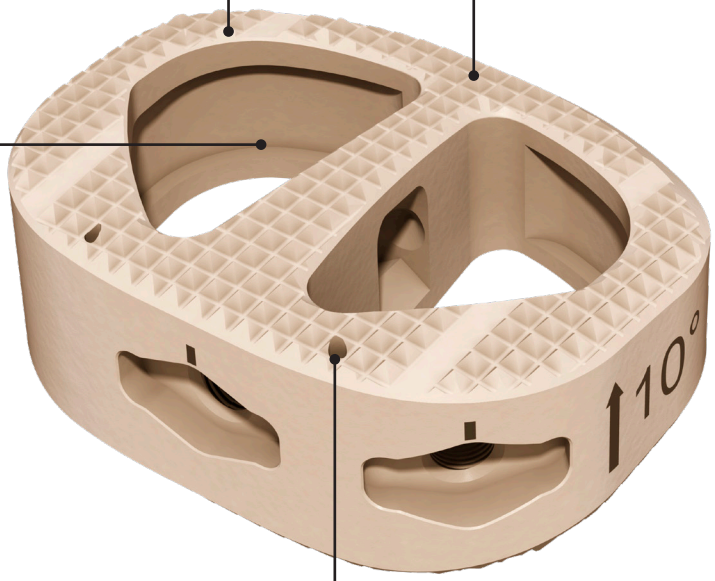
Pyramidal teeth may reduce implant migration

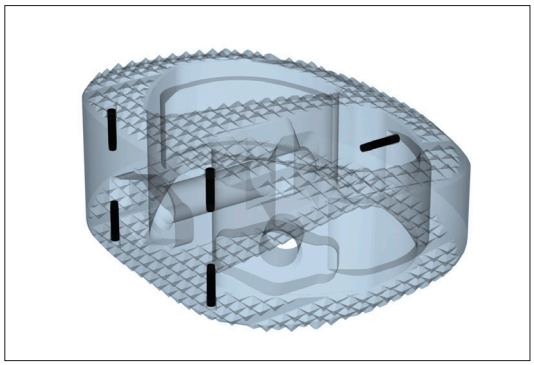
Self-distracting nose

Bulleted nose aids implant insertion

Large graft volume

Undercut and openings to accommodate bone graft material





Tantalum Radiographic Marker Pins

Assist radiographic visualization of implant position

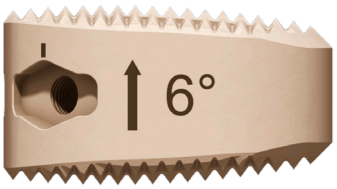
Anatomical shape

The cranial and caudal surfaces of the SYNCAGE Evolution implant are asymmetric and possess a 3D convex shape for endplate contact

Various heights (9, 10.5, 12, 13.5, 15, 17 and 19 mm) support the anatomical fit

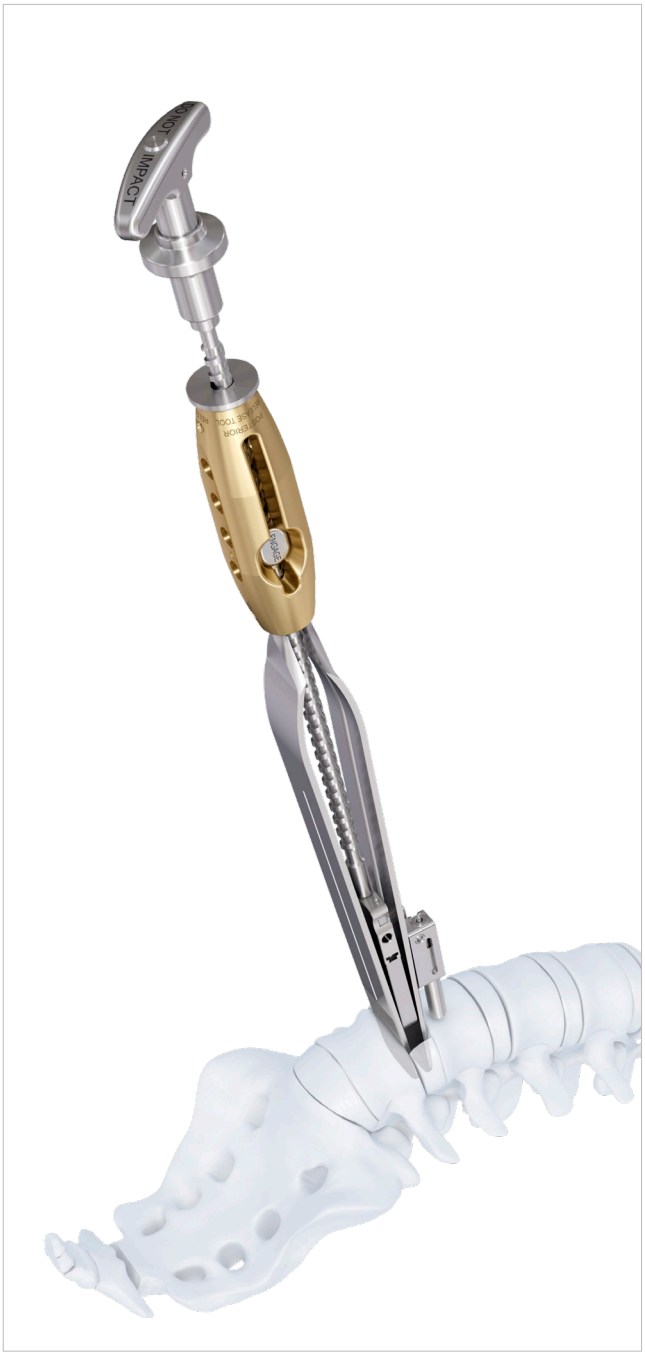
Material

SYNCAGE Evolution Spacer System is manufactured from a biocompatible polymer (Polyetheretherketone (PEEK)) material embedded with Radiopaque Marker Pins, which allow the surgeon to radiographically determine the position of the implant during insertion



Controlled Distraction

- Posterior Release Tool aids progressive and controlled distraction and posterior release
- Changeable inserts for mobilization intended to prevent overdistraction



Insertion with Evolution SQUID

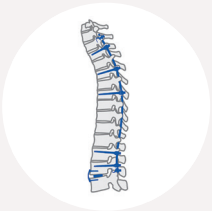
- Evolution SQUID distracts and inserts in one step, without impaction
- Multiple positioning options to recess implant in disc space
- Rails guide implant during insertion

AO Spine Principles

The four principles to be considered as the foundation for proper spine patient management underpin the design and delivery of the Curriculum: Stability, Alignment, Biology, Function.[1,2]

AO Principles[1,2]

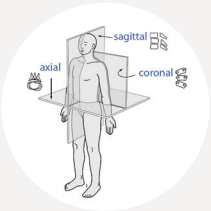
1.



Stability

Stabilization to achieve a specific therapeutic outcome.

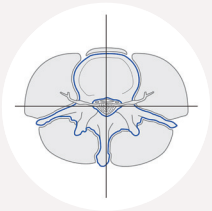
2.



Alignment

Balancing the spine in three dimensions.

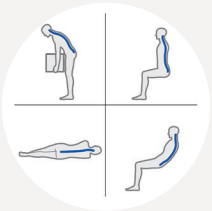
3.



Biology

Etiology, pathogenesis, neural protection, and tissue healing.

4.



Function

Preservations and restoration of function to prevent disability.

Preoperative Planning and Preparation

Required sets	
01.825.001 01.825.004	Instruments for SYNCAGE Evolution, Basic Set Evolution Trial Spacers, Basic Set
or	
01.825.002 01.825.005	Instruments for SYNCAGE Evolution, Standard Set Evolution Trial Spacers, Standard Set
or	
01.825.003 01.825.006	Instruments for SYNCAGE Evolution, Complete Set Evolution Trial Spacers, Complete Set
Optional sets	
01.825.008	Evolution Trial Spacer with Rasp, Basic Set
or	
01.825.009	Evolution Trial Spacer with Rasp, Standard Set
or	
01.825.010	Evolution Trial Spacer with Rasp, Complete Set
01.609.102	Set SYNFRAME™ RL, lumbar
187.310	SYNFRAME™ Basic System in Vario Case
01.600.100	Proprep Set

- Have all necessary imaging studies readily available to plan implant placement and visualize individual patient anatomy.

Have all sets readily available prior to surgery.

Access and Exposure

- The following steps are shown for anterior access, generally below the iliac vessel bifurcation. These can be adopted for anterolateral access above the bifurcation. Regardless the approach, the end goal is midline positioning of the implant in the disc space.

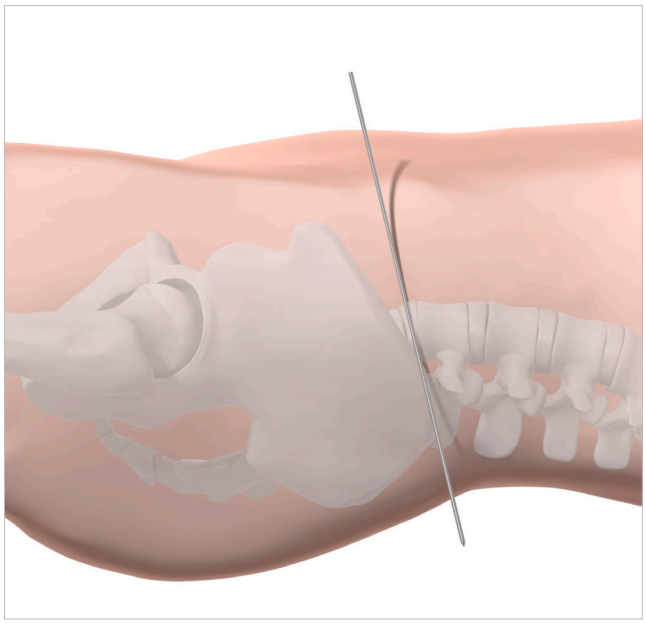
1. Patient positioning

For an anterior approach to the lower lumbar levels, position the patient in a slight Trendelenburg position.

2. Anterior access and approach

Recommended Sets	
01.609.102	Set SYNFRAME RL, lumbar
187.310	SYNFRAME Basic System in Vario Case

The surgical approach depends on the level to be treated. Locate the correct operative disc level and incision location by taking a lateral fluoroscopic view while holding a straight metal instrument at the side of the patient. The appropriate incision location will allow direct visualization into the disc space for midline implant placement.



3. Exposure

Expose the operative disc level through a standard retroperitoneal approach.

For anterior insertion, expose enough of the anterior intervertebral disc to accommodate the width of the implant, centering the planned insertion in the midline. If the vessels and/or tissues cannot be retracted sufficiently, perform insertion from an anterolateral directon.

Discectomy

1. Cut anterior window

Cut a rectangular window into the anterior longitudinal ligament and annulus fibrosus wide enough for implant passage. An Evolution Trial Spacer or Evolution Footprint Trial may be used as a template to determine the width of the window.

- **Retain as much of the anterolateral, lateral and posterior annulus as possible in order to assist the necessary stability of the instrumented segment.**

2. Prepare disc space

Recommended Set	
01.600.100	Proprep Set
Instrument	
03.815.074	Evolution Rasp, dual-sided

Through the window in the annulus fibrosus, excise the disc material and remove the cartilaginous endplates to expose the underlying bony vertebral endplates.

Adequate cleaning of the endplates is important to enable the provision of a vascular supply to the bone graft.

Once the endplates have been prepared, complete additional surgical procedures.

▲ Precaution:

- It is essential that the disc space contents are removed to allow sufficient room for the implant positioning and resulting fusion mass. Residual disc may otherwise be displaced into the spinal canal during implant insertion or compromise fusion within the disc space.

▲ Warnings:

- Excessive cleaning can weaken the endplates by removing bone under the cartilaginous layers. Removal of the entire endplate can cause subsidence and lead to loss of segmental stability.
- Be aware of soft tissue or blood vessels that may be in the pathway of the Evolution Rasp.

Distraction and Segment Mobilization
Option A: Distraction with Spreaders

1. Mobilize segment

Instruments	
SFW650R	Spreader Forceps, curved
SFW550R	Spreader

Under fluoroscopic guidance, insert Spreader in the disc space to distract the intervertebral space in a parallel manner to restore the height and opening of the neural foramina. Ensure the teeth of the Spreader are within the space with good endplate contact.

▲ Warnings

- In order to reduce the risk of endplate fracture it is essential that the tips of the Spreader are placed deep enough in the disc space to the posterior vertebral body margin. In order to ensure this, fluoroscopic guidance is advised during insertion of Spreader.
- It is important not to overdistract the segment as this may lead to injury of ligamentous and neural structures.

Option B: Distraction with Posterior Release Tool

Instruments	
03.825.100	Posterior Release Tool
03.825.101	Insert for Pre-Mobilization, height 10.3 mm, for Posterior Release Tool
03.825.102	Insert for Mobilization, height 12.3 mm, for Posterior Release Tool
03.825.104	Adjustable Stop, for Posterior Release Tool
03.825.105	Strike Cap for Posterior Release Tool
03.825.106	T-Handle, with Hexagonal Coupling, for Posterior Release Tool and Evolution SQUID
SFW602R	Screwdriver for Adjustable Stop
Optional Instrument	
SFW691R	Combined Hammer

1. Assemble Posterior Release Tool

Assemble the Posterior Release Tool according to the disassembly and assembly instruction.

2. Prepare the Posterior Release Tool

2a. Attach the Insert for (Pre-)Mobilization

Release the spindle of the Posterior Release Tool by pushing the release button on the grip and slide the Pusher Block fully back (1). Lock the spindle by pushing the engage button.

Slide the Insert for (Pre-)Mobilization into the Pusher Block until it is fully seated (2).

- The height listed on the Insert for (Pre-)Mobilization refers to the posterior release achieved, once the Insert for Mobilization has been fully engaged.

▲ Warning:

- It is essential to always start with the smallest insert to reduce the risk of overdistraction of the segment and potential injury to the ligamentous and neural structures.

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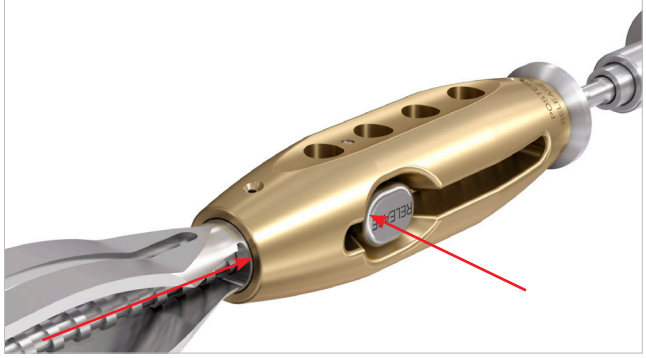


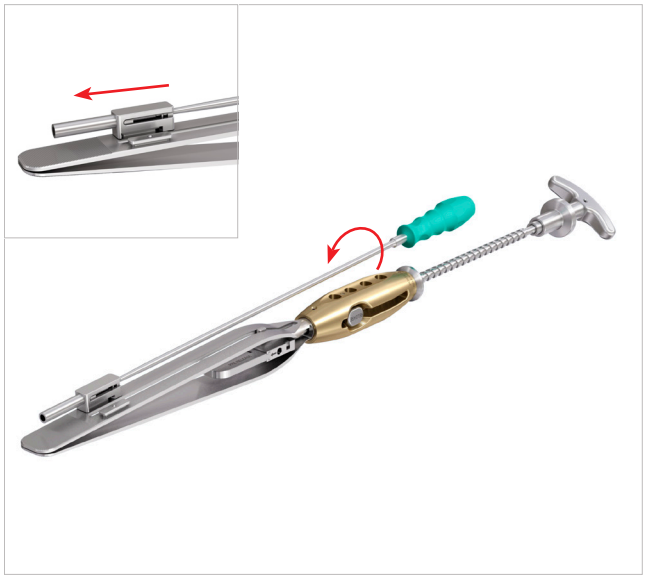
2

2b. Prepare Adjustable Stop

▲ Warning:

- **Attach the Adjustable Stop either on the right or left side depending on the surrounding anatomical structures, e.g., blood vessels.**

Prior to inserting the Posterior Release Tool into the disc space, the Adjustable Stop needs to be fully extended.

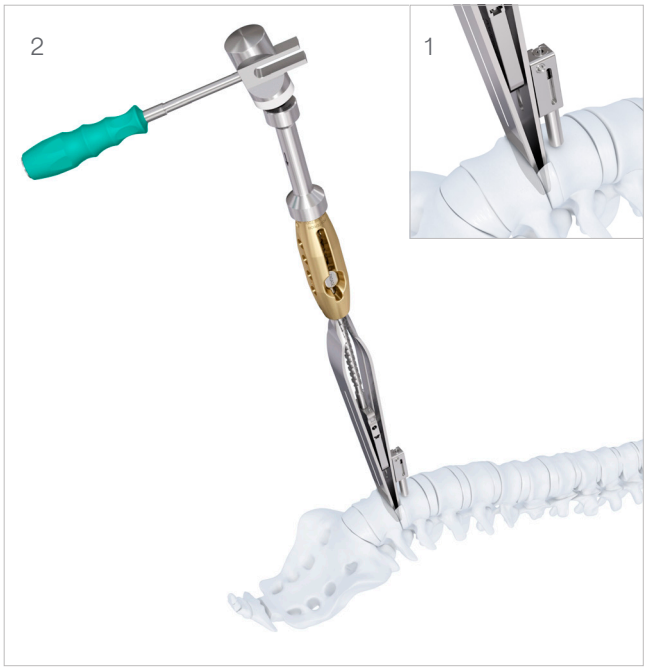


3. Insert the Posterior Release Tool into the disc space

Insert the tip of the Posterior Release Tool into the disc space until the Adjustable Stop on the paddles touches the anterior rim of the vertebral body (1). Ensure that the engage button is depressed to indicate that the spindle is engaged.

Slight hammering on the Posterior Release Tool might be necessary to advance the instrument into the disc space. For hammering remove the T-Handle and place the strike cap onto the proximal end of the Posterior Release Tool (2).

The tip of the instrument should be positioned in the disc space to align with the posterior vertebral body wall. Check the lateral position using the fluoroscopy .



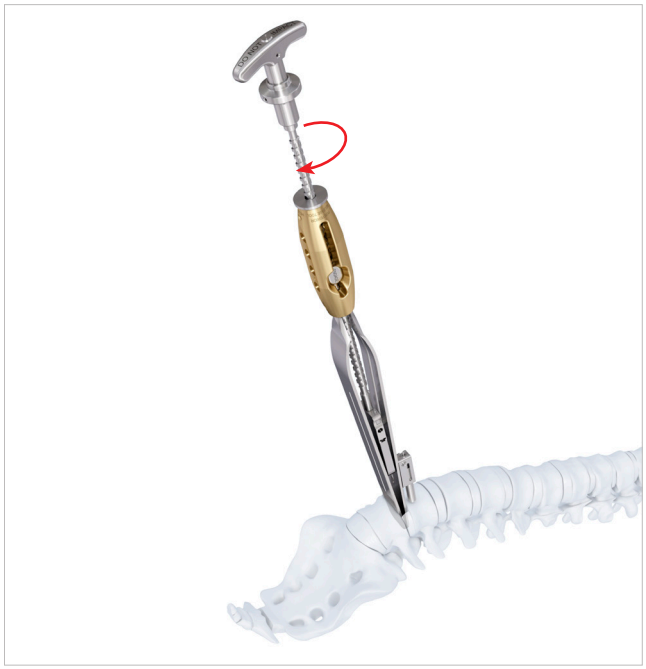
- The Posterior Release Tool can be positioned with the aid of the Adjustable Stop to prevent it from being inserted too far into the intervertebral space. If the Tool must be positioned deeper, the stop can be adjusted using the Screwdriver. One 360° rotation equals 1 mm. The paddle of the Tool is 47.5 mm deep and 30 mm wide.

▲ Precautions:

- A thorough discectomy must be performed prior to insertion of the Posterior Release Tool into the disc space to prevent cartilaginous tissue from being pushed into the spinal canal.
- Be aware of soft tissue or blood vessels that may be in the pathway of the Adjustable Stop or cause possible interference with Retractor Blades.
- Be aware of the Adjustable Stop to reduce the risk of vertebral body damage.
- Placing the tip of the Posterior Release Tool in the disc space to the posterior vertebral body margin is intended to reduce the risk of endplate fracture. The position of the paddles should be monitored by fluoroscopy during insertion of the Posterior Release Tool

4. Engage Posterior Release Tool

With the spindle engaged, turn the T-Handle on the Posterior Release Tool clockwise to advance the insert into the disc space. The force required to turn the T-Handle will increase as the Insert for Mobilization advances down the paddles and the instrument elevates the disc space. Continue turning the T-Handle until the Insert for Mobilization is fully inserted into the disc space and the posterior height listed on the Insert for Mobilization is achieved. If more mobilization is required, a taller Insert for Mobilization should be inserted and the posterior release should be performed accordingly (see section 2a page 15).



Check the amount of distraction by continuously using the image intensifier. The intraoperative change of an Insert for Mobilization can be performed while leaving the Posterior Release Tool inside the disc space.

▲ Warning:

- **It is important to refrain from using an Insert for Mobilization that is too tall, in order to reduce the risk of segment overdistraction as this may lead to injury of ligamentous and neural structures.**

5. Remove Posterior Release Tool

When the distraction has been performed turn back the Insert for Mobilization to its starting position.

▲ Warning:

- It is important to carefully remove the Posterior Release Tool in order to reduce risk of potential injury to adjacent structures.

Trial for Implant Size

1. Trial for footprint size

Instruments	
03.825.080	SYNCAGE Evolution Footprint Trial, small
03.825.081	SYNCAGE Evolution Footprint Trial, medium
03.825.082	SYNCAGE Evolution Footprint Trial, large

Choose an appropriately sized Footprint Trial and insert the Footprint Trial into the disc space. If an anterolateral approach is chosen, use the anterolateral end of the double ended Footprint Trial.

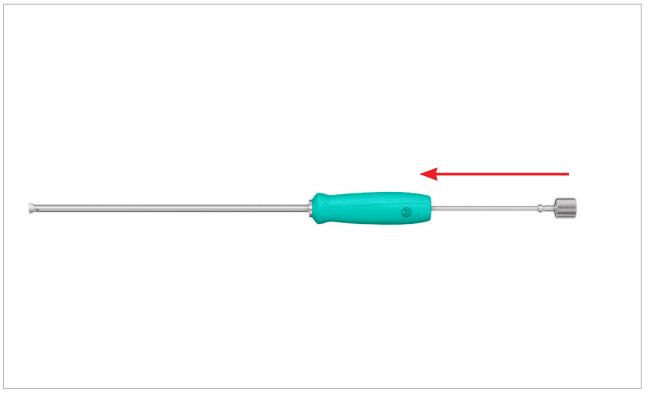
A lateral fluoroscopy is recommended to assess the size of the footprint in relation to the dimensions of the vertebral body.

▲ Warning:

- **Be aware of soft tissue or blood vessels that may be in the pathway of the Footprint Trial or cause possible interference with Retractor Blades.**

2. Assemble Evolution Trial Spacer and Implant Holder

Instruments	
03.815.001	Evolution Trial Spacer and Implant Holder
03.825.002	SYNCAGE Evolution Spindle



Insert the SYNCAGE Evolution Spindle into the cannulated shaft of the Evolution Trial Spacer and Implant Holder.

Option A: Evolution Trial Spacer

3a. Connect Trial Spacer to Evolution Trial Spacer and Implant Holder

Instruments	
03.815.001	Evolution Trial Spacer and Implant Holder
03.825.002	SYNCAGE Evolution Spindle Evolution Trial Spacer

Select the Trial Spacer corresponding to the Footprint size determined by the optional Footprint Trialing or the preoperative planning. Select the height and angle corresponding to the preoperative planning. Attach the chosen Trial Spacer on the Evolution Trial Spacer and Implant Holder according to the particular approach (anterior or anterolateral). Secure the Trial Spacer by fully tightening the knob on the back of the Evolution Trial Spacer and Implant Holder.

▲ Precaution:

- Ensure the lines on the end of the SYNCAGE Evolution Trial Spacer and Implant Holder align with those on the Trial Spacer and that no cross threading occurs. The diamond shaped interface on the Evolution Trial Spacer and Implant Holder must reside within the Trial Spacer interface (1).

1

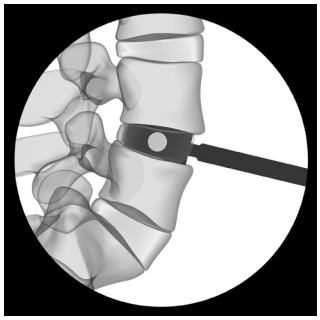
4a. Insert Trial Spacer

Instrument	
SFW691R	Combined Hammer

Insert the Trial Spacer into the disc space. Ensure correct orientation of the Trial Spacer with the arrow on the Trial Spacer pointing cranially. Controlled and light hammering on the Evolution Trial Spacer and Implant Holder may be required to bring the Trial Spacer between the vertebral bodies. If a tight fit is not achieved, repeat the process using an incrementally taller Trial Spacer or a trial with a larger lordotic angle.

Use fluoroscopy to confirm position and fit of the Trial Spacer.

The Combined Hammer can be used to facilitate the insertion or removal of the Trial Spacer.



▲ Warnings:

- Do not leave the Trial Spacer in the disc space.
- Insufficient disc space preparation may compromise vascular supply to the bone graft.
- Ensure proper Trial Spacer handling to avoid instrument breakage in-situ.
- It is essential to always start with the smallest Trial Spacer to reduce the possibility of overdistraction of the segment, which could lead to injury of ligamentous and neural structures.
- Be aware of soft tissue or blood vessels that may be in the pathway of the Trial Spacer or cause possible interference with Retractor Blades.
- Ensure that the Trial Spacer is inserted with the arrow on the Trial Spacer pointing cranially.

Option B: Trial Rasp (optional)

3b. Connect Trial Rasp to Evolution Trial Spacer and Implant Holder

Instruments	
03.815.001	Evolution Trial Spacer and Implant Holder
03.825.002	SYNCAGE Evolution Spindle Evolution Trial Rasp

Select the Trial Rasp corresponding to the footprint size determined by the Footprint Trialing or the preoperative planning. Select the height and angle corresponding to the preoperative planning. Attach the chosen Trial Rasp on the Evolution Trial Spacer and Implant Holder according to the anterior or anterolateral approach. Secure the Trial Rasp by fully tightening the knob on the back of the Evolution Trial Spacer and Implant Holder.

▲ Precaution:

- Ensure the lines on the end of the Evolution Trial Spacer and Implant Holder align with those on the Trial Rasp and that no cross threading occurs. The diamond shaped interface on the Evolution Trial Spacer and Implant Holder must reside within the Trial Rasp interface (2).

2

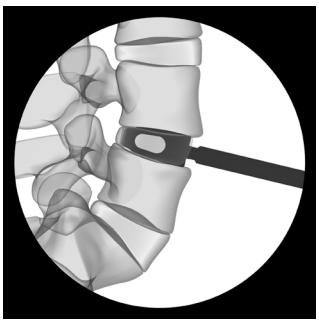
4b. Insert Trial Rasp

Instrument	
SFW691R	Combined Hammer

Insert the Trial Rasp into the disc space. Ensure correct orientation of the Trial Rasp with the arrow on the Trial Rasp pointing cranially. Controlled and light hammering on the Evolution Trial Spacer and Implant Holder may be required to insert the Trial Rasp into the disc space. If a tight fit is not achieved, repeat the process using incrementally larger Trial Rasps or a trial of greater lordotic angle.

Use fluoroscopy to confirm position and fit of the Trial Rasp.

The Combined Hammer can be used to facilitate the insertion or removal of the Trial Rasp.



▲ Warnings:

- Insufficient disc space preparation may compromise vascular supply to the bone graft.
- Excessive rasping can weaken the endplates by removing bone under the cartilaginous layers. Removal of the entire endplate can cause subsidence and lead to loss of segmental stability.
- Ensure proper Trial Rasp handling to avoid instrument breakage in-situ.
- Do not leave the Trial Rasp in the disc space.
- It is essential to always start with the smallest Trial Rasp to reduce overdistraction of the segment and reduce injury of the ligamentous and neural structures.
- Be aware of soft tissue or blood vessels that may be in the pathway of the Trial Rasp or cause possible interference with Retractor Blades.
- Ensure that the Trial Rasp is inserted with the arrow on the Trial Rasp pointing cranially.

Implant Preparation

1. Select SYNCAGE Evolution implant

Select the SYNCAGE Evolution implant that corresponds to the height, Footprint and angle defined using the Trial Spacer or Trial Rasp in the previous steps.

The package of the SYNCAGE Evolution implants and the corresponding Trial Spacer are color-coded.

2. Attach SYNCAGE Evolution implant to Evolution Trial Spacer and Implant Holder and pack implant

Instruments	
03.815.001	Evolution Trial Spacer and Implant Holder
03.825.002	SYNCAGE Evolution Spindle

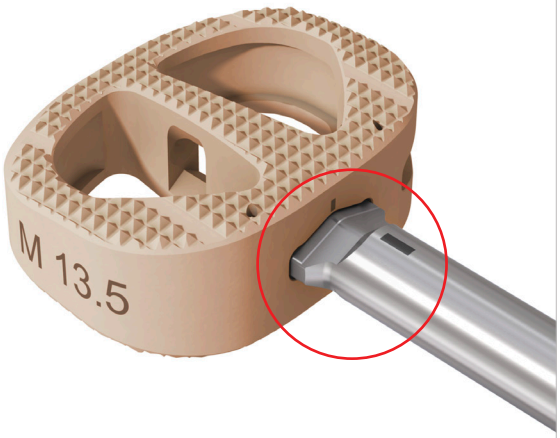
Attach the chosen SYNCAGE Evolution implant to the Evolution Trial Spacer and Implant Holder according to the anterior or anterolateral approach. Secure the SYNCAGE Evolution implant by fully tightening the knob on the back of the Evolution Trial Spacer and Implant Holder.

Pack the interior of the implant with bone graft material.

▲ Precaution:

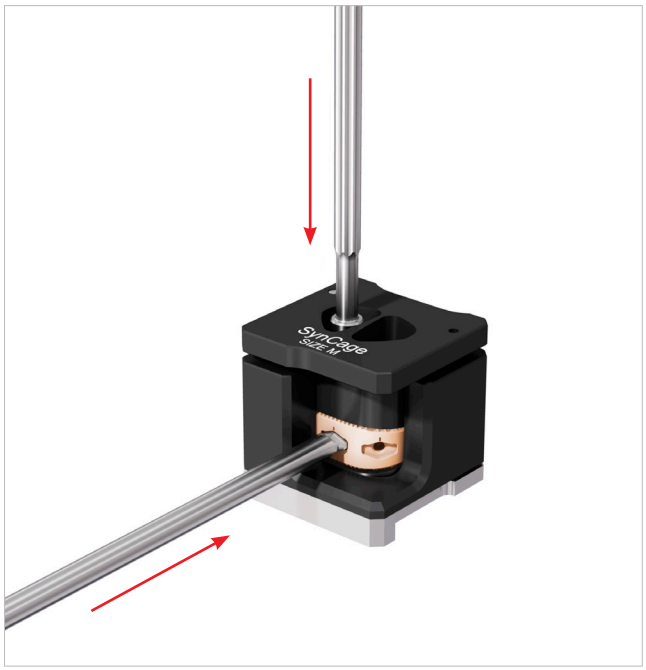
- Ensure the lines on the end of the Evolution Trial Spacer and Implant Holder align with those on SYNCAGE Evolution implant and that no cross threading occurs. The diamond shaped interface on the Evolution Trial Spacer and Implant Holder must reside within the SYNCAGE Evolution implant interface (3).

3



3. Pack SYNCAGE Evolution implant using the Packing Block (optional)

Instruments	
03.815.023	Evolution Graft Packing Tamp, round
03.815.024	Evolution Graft Packing Tamp, oval
03.825.072	Packing Block for SYNCAGE Evolution, small
03.825.073	Packing Block for SYNCAGE Evolution, medium
03.825.074	Packing Block for SYNCAGE Evolution, large



After attaching the SYNCAGE Evolution implant to the Evolution Trial Spacer and Implant Holder, insert it into the appropriate Packing Block.

Fill the SYNCAGE Evolution implant in the Packing Block with bone graft material until the filling material protrudes from its cavities in order to allow enhanced contact with the vertebral endplates.

Use a graft Packing Tamp to firmly pack the filling material into the implant cavities.

▲ Precaution:

- **The Evolution Trial Spacer and Implant Holder must be firmly attached to the implant in order to avoid damage to either the Evolution Trial Spacer and Implant Holder or the SYNCAGE Evolution implant.**

Implant Insertion
Option A: Implant Insertion with Implant Holder

1. Insert SYNCAGE Evolution implant

Instruments	
03.815.001	Evolution Trial Spacer and Implant Holder
03.825.002	SYNCAGE Evolution Spindle
SFW691R	Combined Hammer

Verify the connection of the Evolution Trial Spacer and Implant Holder to the SYNCAGE Evolution implant. Ensure the correct direction of the SYNCAGE Evolution implant with the arrow on the SYNCAGE Evolution implant pointing cranially. Insert the SYNCAGE Evolution implant into the disc space according to the anterior or anterolateral approach. Controlled and light hammering on the Evolution Trial Spacer and Implant Holder may be required to advance the SYNCAGE Evolution implant into the intervertebral disc space. The SYNCAGE Evolution implant must fit firmly with a tight press-fit between the endplates.

Use fluoroscopy to confirm SYNCAGE Evolution implant position as well as resulting disc height and overall alignment.

▲ Precaution:

- **Ensure that the arrow on the SYNCAGE Evolution implant is pointing cranially during insertion.**

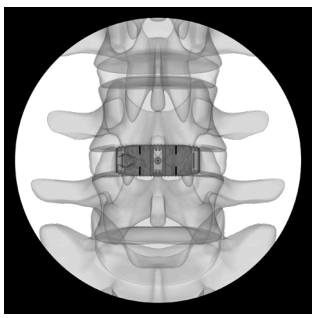
2. Remove Evolution Trial Spacer and Implant Holder

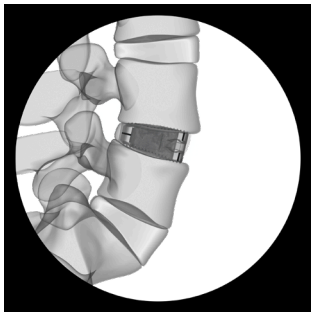
After the SYNCAGE Evolution implant is correctly positioned, loosen the knob of the Evolution Trial Spacer and Implant Holder in order to release the connection to the SYNCAGE Evolution implant. Remove the Evolution Trial Spacer and Implant Holder.

3. Verify placement

The desired position for the SYNCAGE Evolution implant is centered within the periphery of the vertebral endplate.

Verify the location of the SYNCAGE Evolution implant relative to the vertebral bodies in the AP and lateral positions under fluoroscopy. Five X-Ray markers are incorporated into the SYNCAGE Evolution implant to assist in intra-operative radiographic assessment of the position of the SYNCAGE Evolution implant. The posterior X-Ray marker is located horizontally and indicates the posterior wall of the SYNCAGE Evolution implant.





Option B: Insertion with Evolution SQUID

1. Assemble the Evolution SQUID

Instruments	
03.815.030	Evolution SQUID, Synthes Quick Inserter and Distractor
03.815.029	Evolution SQUID Assembly/ Disassembly Tool
03.825.106	T-Handle, with Hexagonal Coupling, for Posterior Release Tool and Evolution SQUID

Assemble the Evolution SQUID according to the disassembly and assembly instructions.

2. Prepare the Evolution SQUID

Instruments	
03.815.030	Evolution SQUID, Synthes Quick Inserter and Distractor
03.815.035	Evolution SQUID, Push Block, Flush 0.0 mm
03.815.036	Evolution SQUID, Push Block, Recessed 3.0 mm
03.815.037	Evolution SQUID, Push Block, Proud 3.0 mm

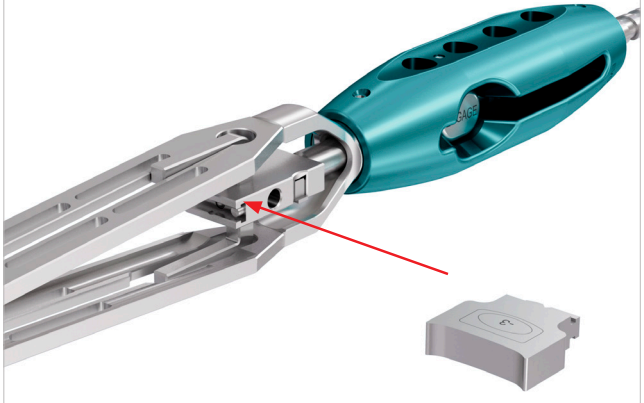
Push the release button on the Evolution SQUID grip to release the spindle for the Pusher Block (1). Slide the Pusher Block fully back toward the grip and then push the engage button to lock the spindle (2). Slide a Push Block into the Pusher Block coupling until it is fully seated (3).

- Use of the Push Block, Proud will leave the implant protruding 3 mm from the end of the depth-stops of the Evolution SQUID, Synthes Quick Inserter and Distractor.
- Use of the Push Block, Flush will leave the implant flush with the end of the depth-stops of the Evolution SQUID, Synthes Quick Inserter and Distractor.
- Use of the Push Block, Recessed will leave the implant recessed 3 mm from the end of the depth-stops of the Evolution SQUID, Synthes Quick Inserter and Distractor.

1

2

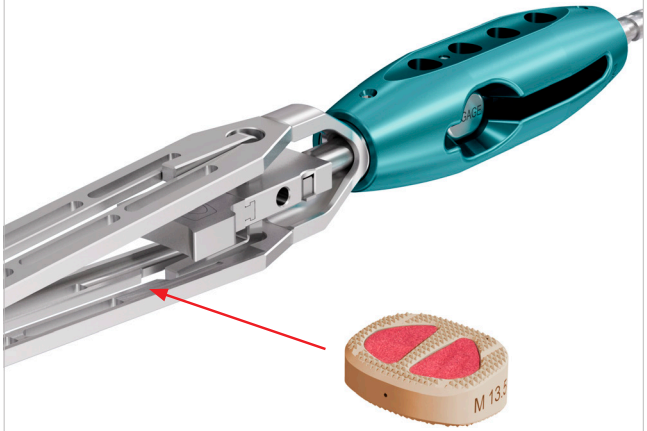
3



Insert the SYNCAGE Evolution implant in between the paddles of the Evolution SQUID so that the grooves of the SYNCAGE Evolution implant connect to the rails of the blades (4). Turn the T-Handle of the Evolution SQUID clockwise to advance the Push Block until it contacts the SYNCAGE Evolution implant (5). The SYNCAGE Evolution implant is now held securely in place and is ready for insertion.

- **The tip of the paddles will be inserted into the disc space up to the depth-stops on the paddles. To facilitate full insertion, the tip must be fully closed.**

4



5

3. Insert the Evolution SQUID into the disc space

Insert the tip of the Evolution SQUID into the disc space until the depth-stops on the paddles touch the anterior rim of the vertebral body. The tip of the Evolution SQUID is 25 mm deep and 28 mm wide. To ensure that the SYNCAGE Evolution implant is inserted symmetrically into the disc space, the central opening of the Evolution SQUID paddles should be aligned with the anterior midline of the vertebral bodies.

▲ Precaution:

- **Ensure that the Evolution SQUID is inserted with the arrow on the SYNCAGE Evolution implant pointing cranially.**

4. Insert the SYNCAGE Evolution implant

With the spindle engaged, turn the T-Handle on the Evolution SQUID to advance the implant down the paddles and into the disc space (1). The force required to turn the T-Handle will increase as the SYNCAGE Evolution implant advances down the paddles and the Evolution SQUID elevates the disc space. Under fluoroscopic control continue turning the T-Handle until the SYNCAGE Evolution implant is fully ejected and released from the Evolution SQUID (2). A click, as the paddles close, confirms that the SYNCAGE Evolution implant is seated and the Evolution SQUID is fully ejected and released. Depending on the size of the vertebrae, the anterior edge of the SYNCAGE Evolution implant will usually be recessed +/-1 mm to the amount listed on the chosen Push Block.

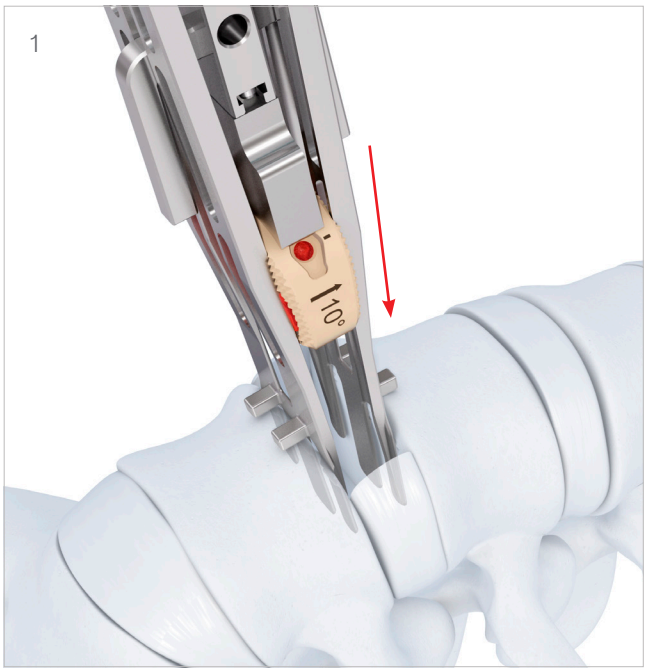
▲ Precautions:

- The Evolution SQUID can only be used for a direct anterior approach.
- Use fluoroscopy to confirm the position of Evolution SQUID and the SYNCAGE Evolution implant, restoration of disc and foraminal height, and overall alignment.

▲ Warnings:

- The implant, as well as the SQUID Stop, are moving toward the vertebral body. Be aware of soft tissue and blood vessels that may be in the pathway of the implant and the SQUID Stop, as they may be pushed against the vertebral bodies or interfere with Retractor Blades. Non-observance can lead to injuries on adjacent structures.
- Do not use an implant that is too large in size for the disc space as overdistraction of the segment may result in injury to the ligamentous and neural structures.

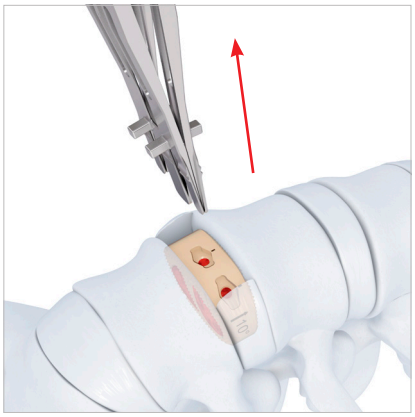
1



2

5. Remove Evolution SQUID

When the SYNCAGE Evolution implant is correctly positioned carefully remove the Evolution SQUID.

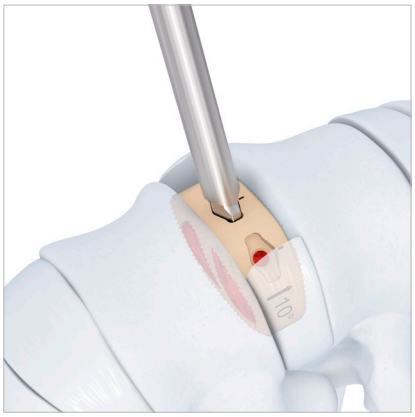


▲ Warning:

- **Be aware of soft tissue or blood vessels that may be in the pathway of the Evolution SQUID or cause possible interference with Retractor Blades.**

6. Final SYNCAGE Evolution implant positioning (optional)

Instruments	
SFW691R	Combined Hammer
03.815.001	Evolution Trial Spacer and Implant Holder

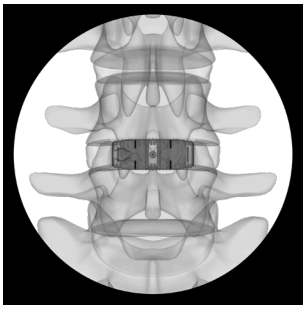


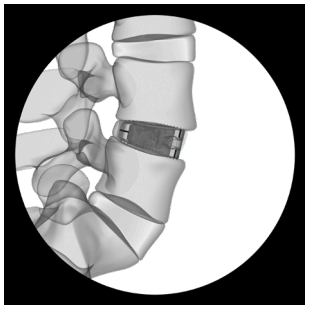
In case the SYNCAGE Evolution implant needs to be repositioned use the Evolution Trial Spacer and Implant Holder. Attach the Evolution Trial Spacer and Implant Holder and lightly hammer using the Combined Hammer.

Use fluoroscopic control during the repositioning of the implant.

7. Verify placement

The desired position for the SYNCAGE Evolution implant is centered within the periphery of the vertebral endplate.





Verify the location of the SYNCAGE Evolution implant relative to the vertebral bodies in the AP and lateral directions under fluoroscopy. Five X-Ray markers are incorporated into the SYNCAGE Evolution implant to assist in intraoperative radiographic assessment of the position of the SYNCAGE Evolution implant. The posterior X-Ray marker is located horizontally and is flush against the posterior wall of the SYNCAGE Evolution implant.

Supplemental Fixation

Supplemental Fixation

▲ **Precaution:**

- The SYNCAGE Evolution implant is intended to be used with supplemental anterior and/or posterior fixation.

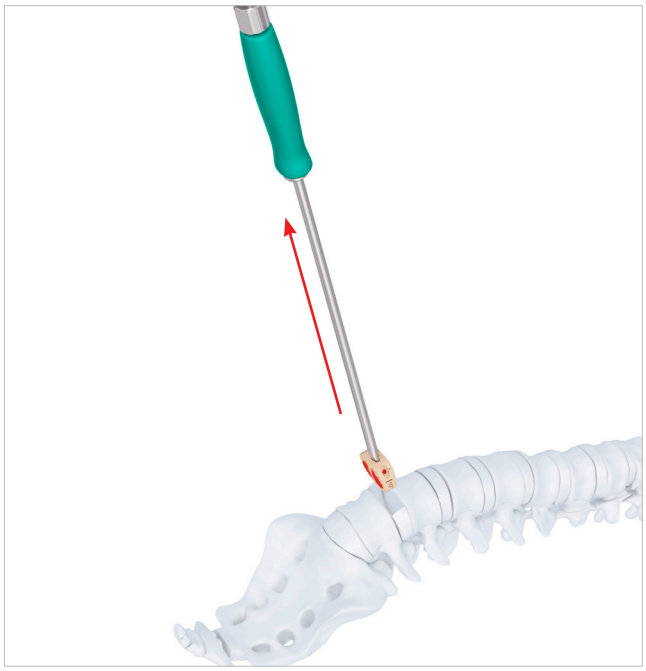
Implant Removal
Option A: Removal with Implant Holder

1. Approach the SYNCAGE Evolution implant

Instrument	
03.815.001	Evolution Trial Spacer and Implant Holder
03.825.002	SYNCAGE Evolution Spindle

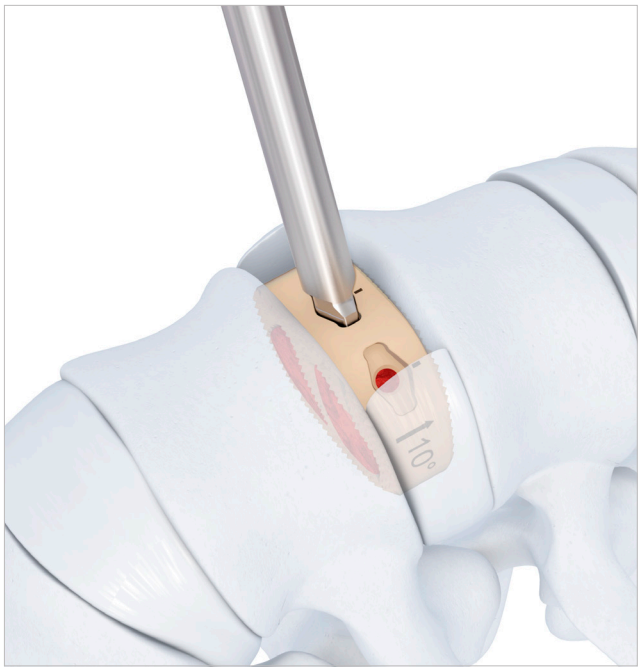
If implant removal is necessary, the removal should be first attempted with the Evolution Trial Spacer and Implant Holder.

If the accessibility of the diamond shaped interface is limited due to bony or soft tissue structures, remove them with appropriate instruments or try an anterolateral access.



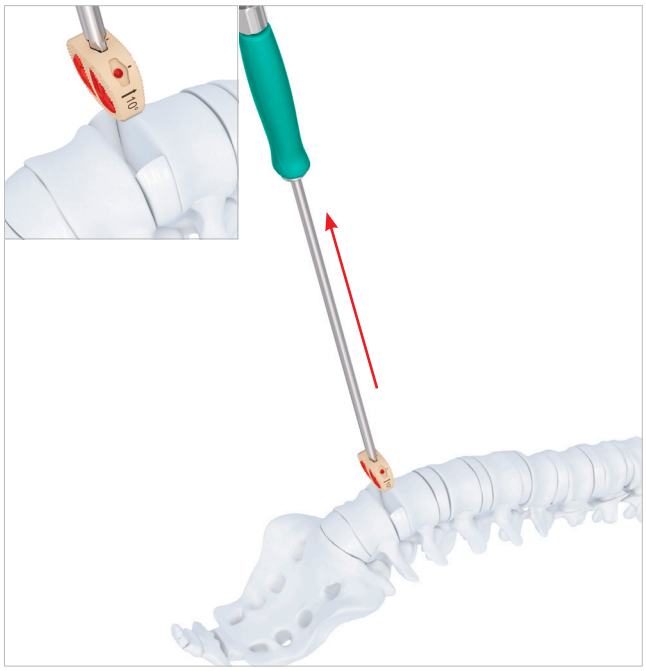
2. Attach the Evolution Trial Spacer and Implant Holder

Engage the diamond shaped interface with the Evolution Trial Spacer and Implant Holder.



3. Remove SYNCAGE Evolution implant

Apply an extraction force to the Evolution Trial Spacer and SYNCAGE Evolution Implant Holder to remove the SYNCAGE Evolution implant.



▲ Precaution:

- After removal of the SYNCAGE Evolution implant, verify that the removed implant is intact.

▲ Warning:

- Do not reuse SYNCAGE Evolution implants.

Option B: Removal with Holding Forceps

1. Approach SYNCAGE Evolution implant

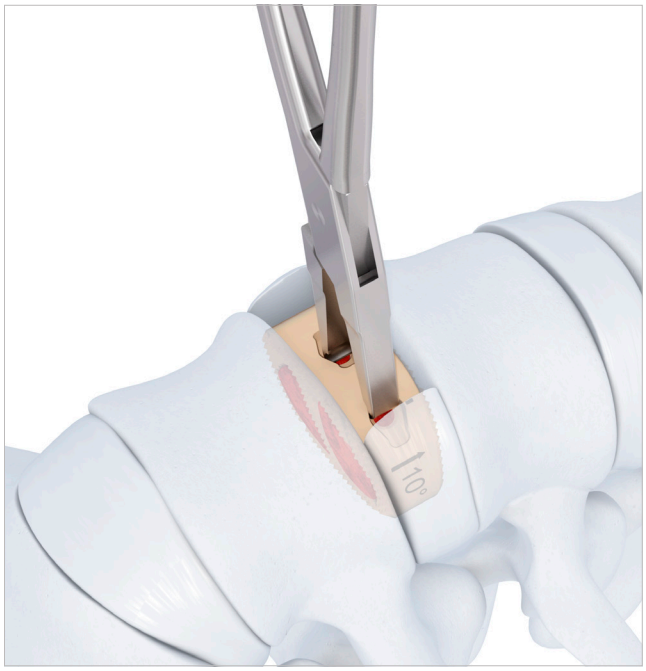
Instrument	
388.407	Holding Forceps for Rods 3.5 mm, length 181 mm

If SYNCAGE Evolution implant removal is necessary, the Holding Forceps can be used.

- **If the accessibility of the interface is limited due to bony or soft tissue structures, remove them with appropriate instruments.**

2. Connect Holding Forceps to SYNCAGE Evolution implant

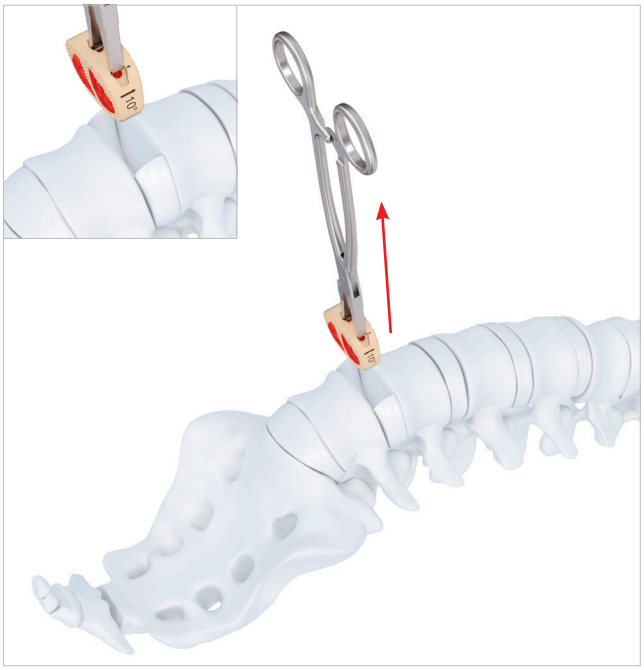
Engage the anterior and anterolateral diamond shaped interface with the Holding Forceps.



3. Remove SYNCAGE Evolution implant

Apply a gentle extraction force to the Holding Forceps to remove the SYNCAGE Evolution implant. After removal of the SYNCAGE Evolution implant, ensure that all components were removed from the intervertebral disc space.

- **SYNCAGE Evolution implants are not intended for re-use.**



Indications and Contraindications

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