

CAVITY CREATION INSTRUMENT

For the creation of a void in
cancellous bone in the spine

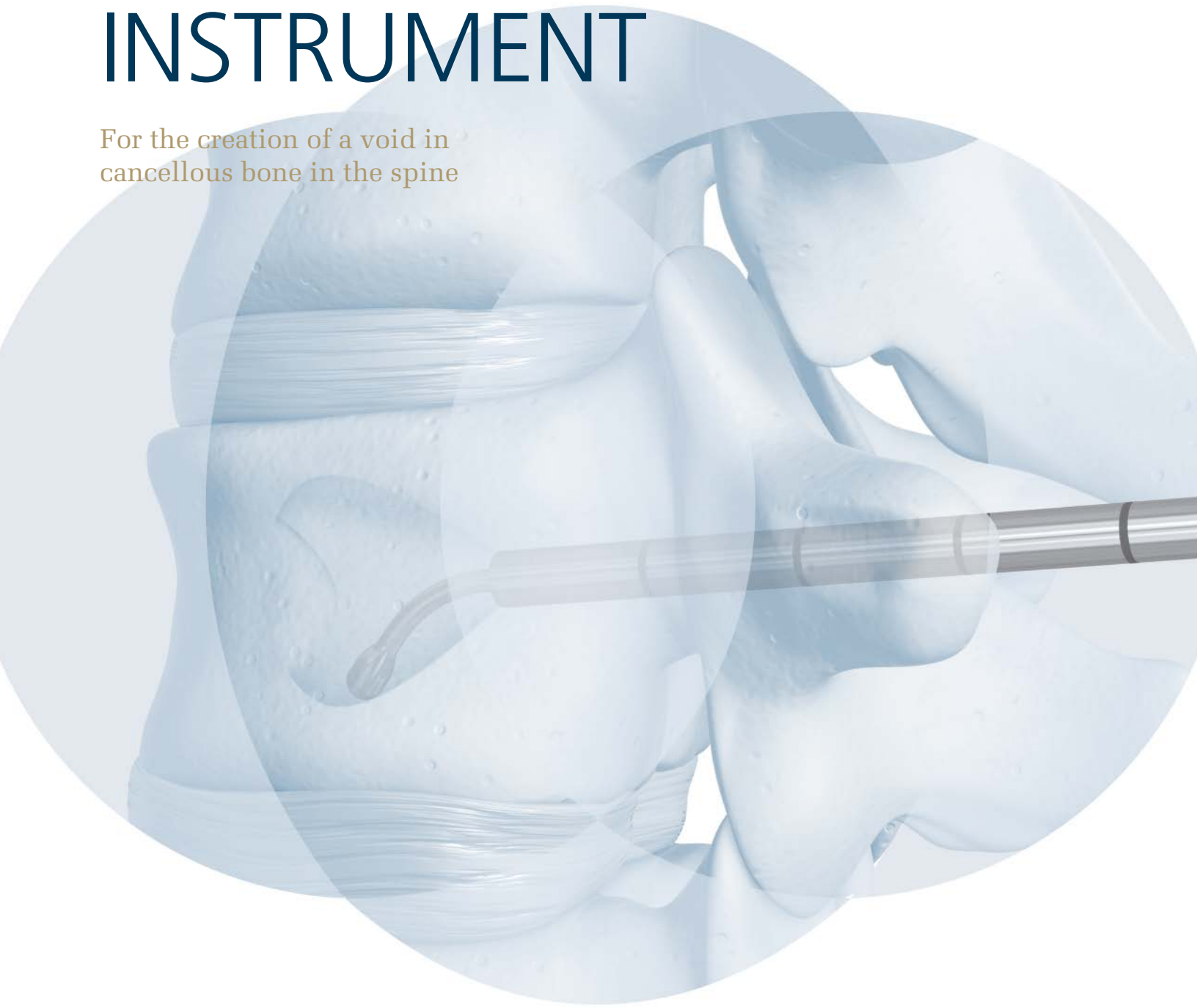


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CAVITY CREATION INSTRUMENT

For the creation of a void in cancellous bone in the spine.

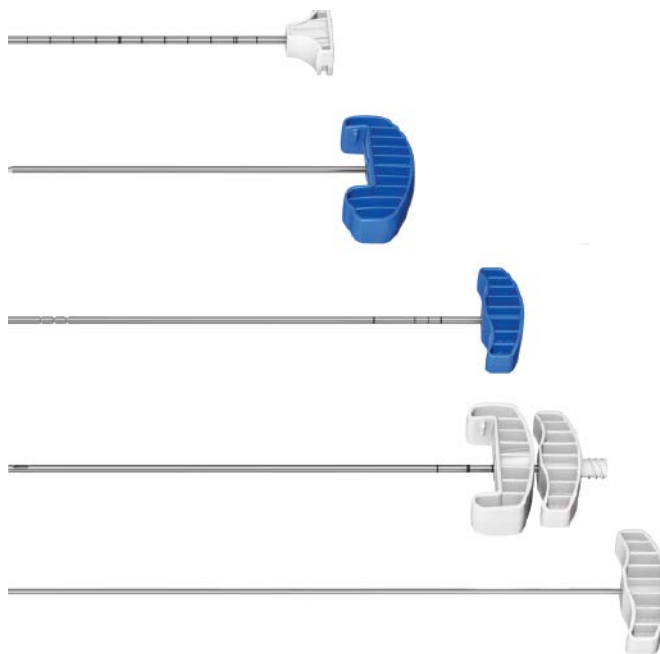
Cavity Creation Instrument

- For the creation of a void in the cancellous bone in the spine
- Two sizes to fit varying patient anatomy
- Adjustable stop allows control of insertion depth



Access Kit

- Single step access
- Two access needle options: diamond and bevel tip
- Two injection needle options: side and end opening
- Optional biopsy kit available
- Optional drill available



AO PRINCIPLES

In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation.¹ They are:

- Anatomic reduction
- Stable internal fixation
- Preservation of blood supply
- Early, active mobilization

The fundamental aims of fracture treatment in the limbs and fusion of the spine are the same. A specific goal in the spine is returning as much function as possible to the injured neural elements.^{2,3}

1. Müller ME, Allgöwer M, Schneider R, Willenegger R. *Manual of Internal Fixation*. 3rd ed. Berlin Heidelberg New York: Springer. 1991.
2. Ibid.
3. Aebi M, Thalgott JS, Webb JK. *AO ASIF Principles in Spine Surgery*. Berlin; Springer-Verlag, 1998.

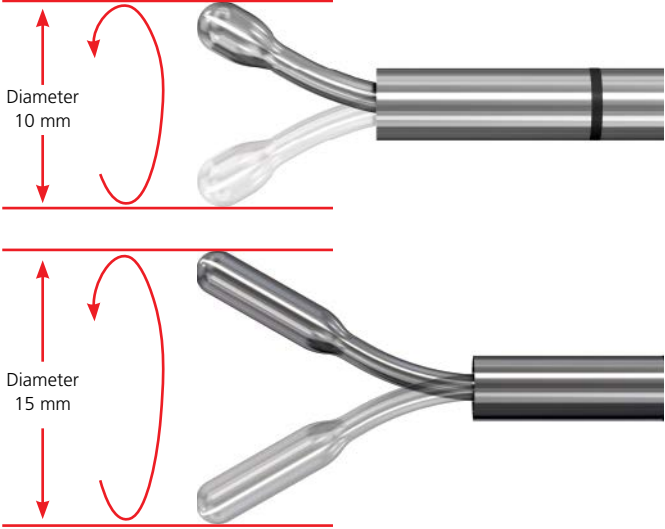
PRODUCT SELECTION

Product Selection

Cavity Creation Instrument









The Cavity Creation Instrument is available in two sizes. The size is based on the maximum diameter if the instrument is rotated a full 360 degrees.

Product Number	Diameter
03.702.750S	10 mm
03.702.751S	15 mm



Access Kit

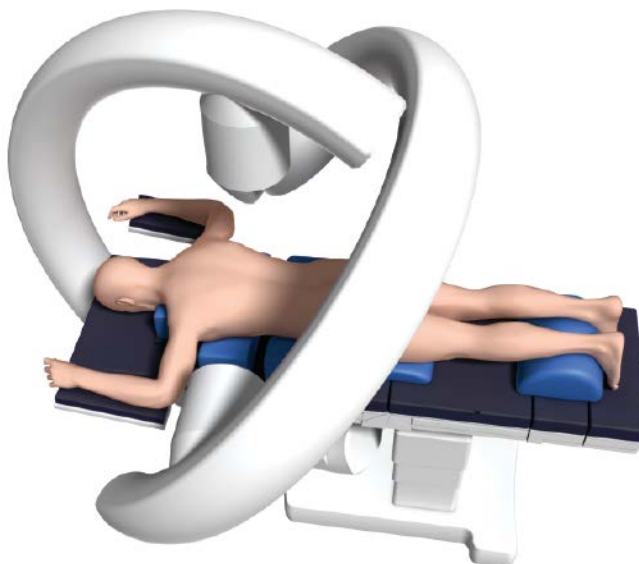
There are four options for the Access Kit. The difference between the two kits involves the style of access instrument and cement injection needle.

Product Number	Access Instrument Tip	Cement Injection Needle
03.804.517S		
03.804.518S		
03.804.519S		
03.804.520S		

PATIENT POSITIONING

Position patient

- Place the patient in the prone position on a radiolucent table to allow imaging of the targeted/affected levels. Anteroposterior (AP) and lateral fluoroscopy are used frequently throughout the procedure. Biplanar fluoroscopy is recommended for the most efficient use of imaging. A single, freely mobile C-arm may also be used. Use of a device that offers a high-quality image is required. Set up the table, patient, and fluoroscopy to facilitate AP and lateral imaging throughout the procedure.



APPROACH

1

Approach

Instruments

03.804.517S Access Kit, 10 Gauge,
Diamond Tip/End Opening, Sterile

03.804.518S Access Kit, 10 Gauge,
Bevel Tip/End Opening, Sterile

03.804.519S Access Kit, 10 Gauge,
Diamond Tip/Side Opening, Sterile

03.804.520S Access Kit, 10 Gauge,
Bevel Tip/Side Opening, Sterile



Transpedicular approach

- ① The access instruments can be inserted through either a transpedicular or extrapedicular approach. Identify the anatomical landmarks of the affected segment(s) under imaging.

Option A: Transpedicular

- ① Under fluoroscopy, determine the location of the incision. The incision should facilitate insertion directly through the pedicle.

Important: Do not breach the pedicle wall or anterior cortical wall of the vertebral body during the approach.

Make a stab incision.

- ① Under fluoroscopy, insert the tip of the access instrumentation through the incision until it contacts the pedicle. Confirm the proper trajectory, then advance the instrumentation through the pedicle until the working cannula just passes the posterior wall of the vertebral body. If a biopsy is desired, continue to Step 2, if a biopsy is not desired, continue to Step 3.

- ① **Tip:** Ensure that the tip of the access instrumentation does not pass the medial wall of the pedicle in the AP view until it has passed the posterior wall of the vertebral body in the lateral view to avoid entering the spinal canal.

For bilateral procedures, repeat on the contralateral side.

Option B: Extrapedicular

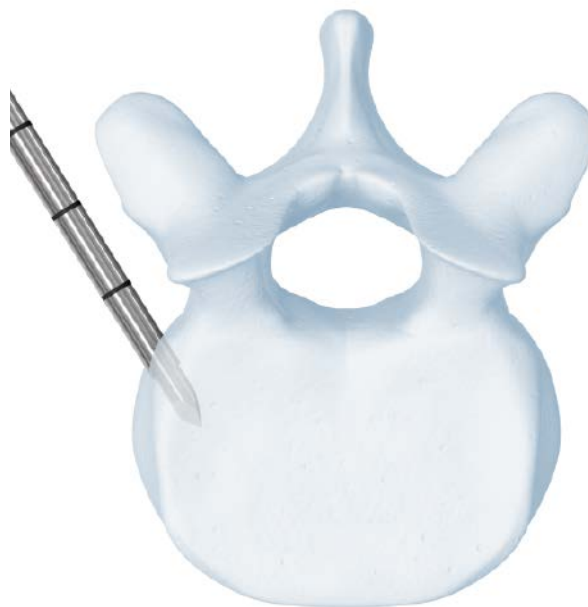
- 1 Under fluoroscopy, determine the location of the incision. The trocar assembly should enter the vertebral body lateral to the pedicle.

Important: Do not breach the anterior cortical wall of the vertebral body during the approach.

Make a stab incision.

- 2 Under fluoroscopy, insert the tip of the access instrumentation through the incision until it contacts the posterolateral border of the vertebral body. Confirm the proper trajectory, and then advance the instrumentation until the working sleeve just passes the posterior wall of the vertebral body. If a biopsy is desired, continue to Step 2; if a biopsy is not desired, continue to Step 3.

For bilateral procedures, repeat on the contralateral side.



Extrapedicular approach

BIOPSY

2

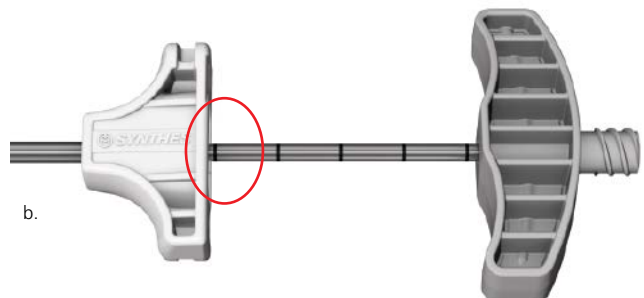
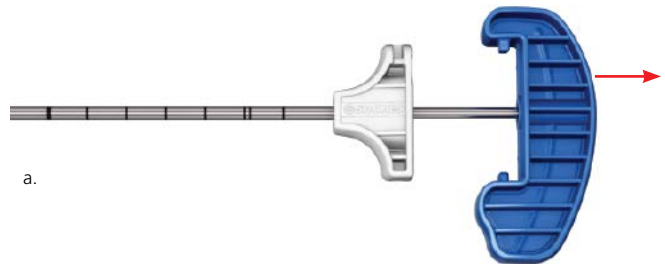
Biopsy

Instruments

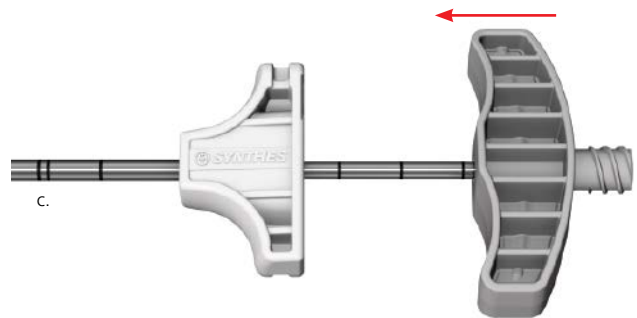
03.804.521S Biopsy Kit, 10G, Sterile

ⓘ **Note:** These steps must be performed under fluoroscopy.

- a. Once the construct has passed the posterior wall of the vertebral body, hold the working sleeve (white handle) in place and carefully rotate the trocar (blue handle) counter-clockwise to unlock it from the working sleeve. Remove the trocar from the working sleeve.
- b. Insert the biopsy needle into the working sleeve until the first marker reaches the handle of the working sleeve. In this position, the tip of the biopsy needle is at the tip of the working sleeve.



-
- c. Slowly advance the biopsy needle to the final position in the anterior half of the vertebral body. Do not use a hammer, and avoid perforating the anterior wall. Bone tissue will be captured in the biopsy needle.
 - d. Once the needle reaches the final position, rotate the biopsy needle one full turn (360°) to ensure that the bone biopsy is fully loosened from the surrounding bone. Optionally, attach a standard syringe (1 cc–3 cc) to the Luer-Lock of the biopsy needle and slowly draw the syringe.
 - e. Remove the biopsy needle with the optionally attached syringe from the working sleeve.
 - f. If used, remove the syringe from the biopsy needle.
 - g. Use the stylet to push the collected bone tissue out of the biopsy needle.
 - h. Insert the trocar back into the working sleeve and lock it in place by rotating the blue handle clockwise.
 - i. Continue on to Step 3: Access.



ACCESS

3

Access

- Under fluoroscopy, insert the access construct until the working sleeve is approximately 10 mm into the vertebral body.

Note: The cavity creation instrument will begin to create a cavity at the distal end of the working sleeve. Position the working sleeve where cavity creation should begin.

- If necessary, carefully hammer only on the blue handle of the trocar to gently advance the trocar instrumentation.

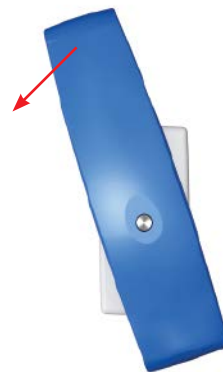
Important: Ensure that the trocar instrumentation does not breach the anterior wall of the vertebral body.

- Confirm proper positioning of the access instrumentation under both AP and lateral fluoroscopy. Hold the working sleeve (white handle) in place and carefully rotate the trocar (blue handle) counterclockwise to unlock it from the working sleeve. Remove the trocar, leaving the working sleeve in the vertebral body.

For bilateral procedures, repeat on the contralateral side.

Warnings:

- Do not insert or advance the working sleeve in the bone without the trocar. This could damage the working sleeve and obstruct instrument insertion.
- Do not redirect the instrument assembly without removing it and reaccessing the vertebral body.



CREATE THE CAVITY

4

Create the Cavity

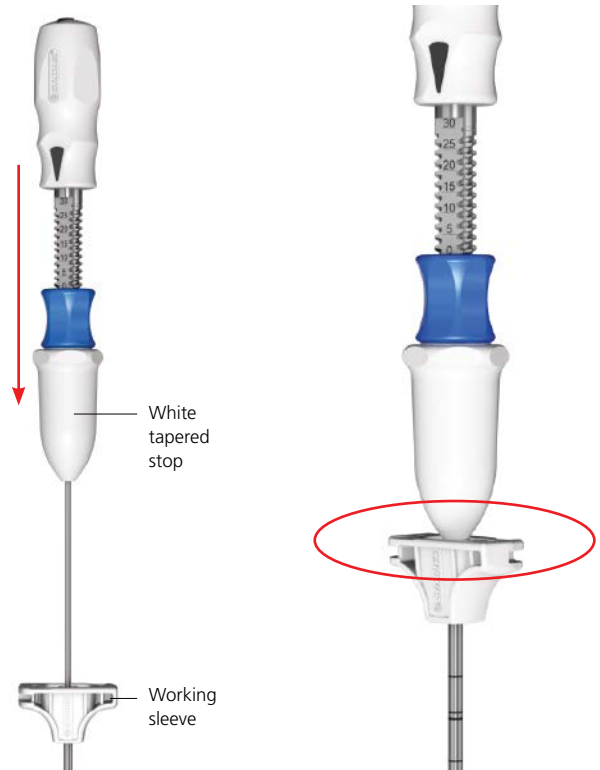
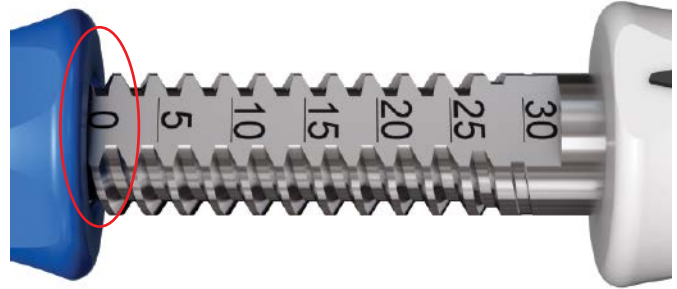
Instruments

03.702.750S Cavity Creation Instrument, 10 mm, Sterile

03.702.751S Cavity Creation Instrument, 15 mm, Sterile

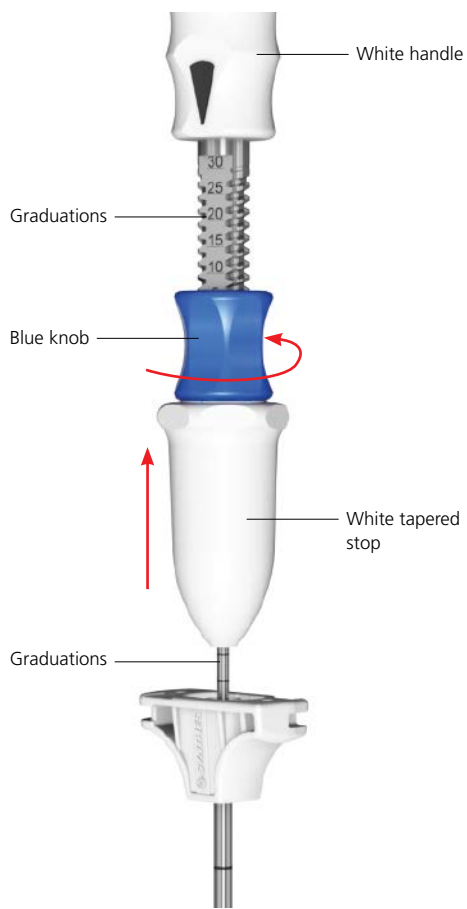
Confirm the Cavity Creation Instrument is at the "0" position prior to use.

- While firmly holding the working sleeve, insert the Cavity Creation Instrument into the working sleeve until the white-tapered stop contacts the working sleeve. In this position, the tip of the Cavity Creation Instrument is at the distal end of the working sleeve.



Create the Cavity

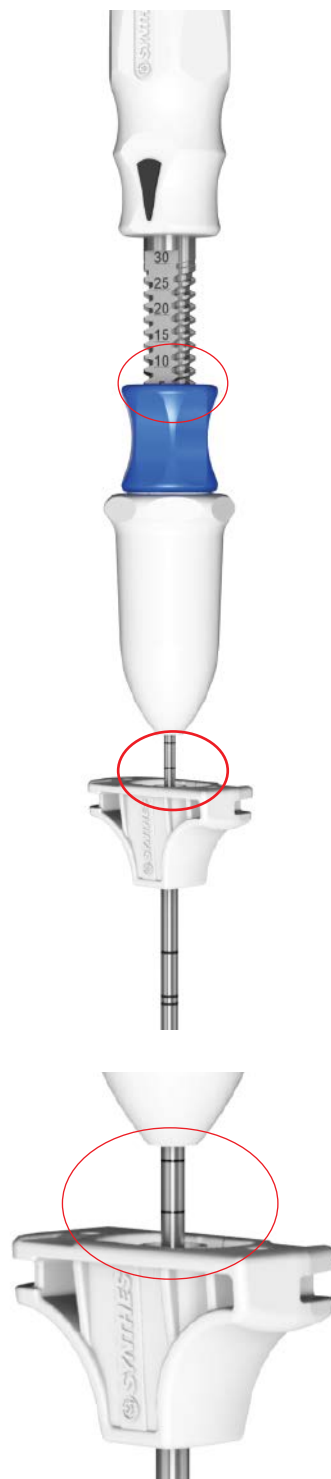
The blue knob controls the position of the white-tapered stop. While holding the white handle in place with one hand, turn the blue knob counter-clockwise with the other hand to set the stop position to the position desired for initial insertion.



Create the Cavity

Monitor the graduations on both the threaded shaft and wire while turning the blue knob. In order to deploy just the curved portion of the tip initially, set the stop to approximately 5 mm.

Note: Depth graduations appear on both the wire and threaded shaft.



- Under fluoroscopy, while holding the working sleeve with one hand, carefully advance the Cavity Creation Instrument into the working sleeve using the white handle, which will advance the curved tip out of the distal end of the sleeve into the vertebral body.

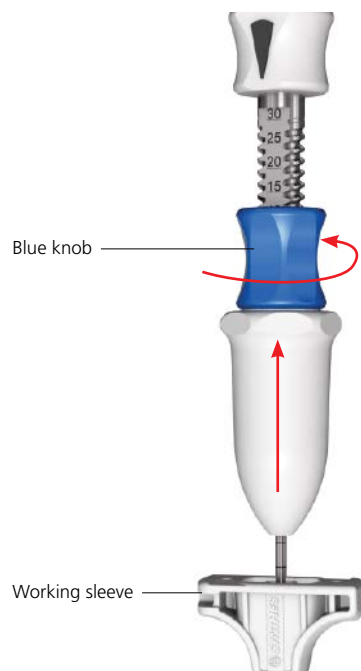
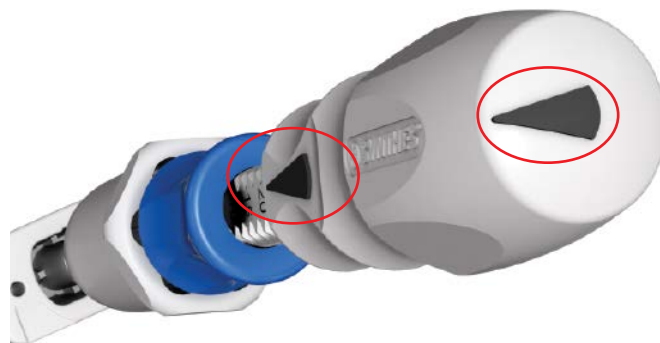
Note: The optional drill (03.804.521S) can be used to clear a path for the initial introduction of the Cavity Creation Instrument if necessary.



Note: The arrows on the handle indicate the position of the curved tip.

- Once the tip is deployed, the blue knob can be used to adjust the stop position of the instrument. This will allow the tip to be advanced into the vertebral body to the desired distance. Carefully monitor tip advancement under fluoroscopy.

Warning: Do not advance the working sleeve with the Cavity Creation Instrument.



During the procedure, the white handle can be used to rotate the curved tip within the vertebral body and move the tip along the axis of the cannula to create the desired cavity. Always monitor the tip position under fluoroscopy and monitor the stop position using the scale on the threaded shaft.

Note: Carefully turn the handle, initially in increments, while observing the tip under fluoroscopy to ensure the tip is creating a cavity.

Warnings:

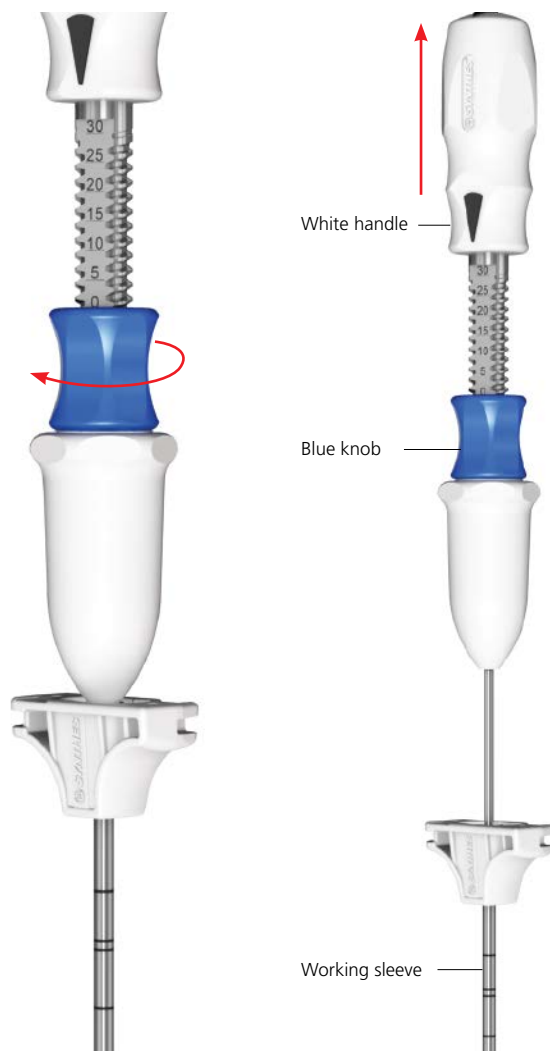
- Do not hold the blue knob while turning the white handle. This may inadvertently advance the tip of the Cavity Creation Instrument.
- Avoid bending the instrument while creating the cavity.



- Once the desired cavity has been created, hold the working sleeve firmly and pull the Cavity Creation instrument out of the working sleeve using the white handle. Before reinserting the instrument back into a cannula, rotate the blue knob to set the instrument back to the "0" position. Alternatively, once the desired cavity has been created, rotate the blue knob to set the instrument back to the "0" position. Hold the working sleeve firmly and pull the Cavity Creation instrument out of the working sleeve using the white handle.

Important: The metal tip is not implant grade material. If tip breakage occurs, all fragments must be retrieved from the patient.

For bilateral procedures, repeat on the contralateral side.



INJECT PMMA BONE CEMENT

5

Inject PMMA Bone Cement

Instruments

03.804.517S Access Kit, 10 Gauge,
Diamond Tip/End Opening, Sterile

03.804.518S Access Kit, 10 Gauge,
Bevel Tip/End Opening, Sterile

03.804.519S Access Kit, 10 Gauge,
Diamond Tip/Side Opening, Sterile

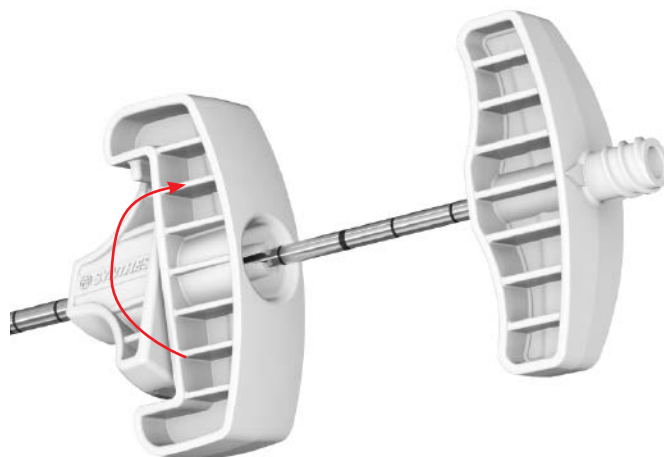
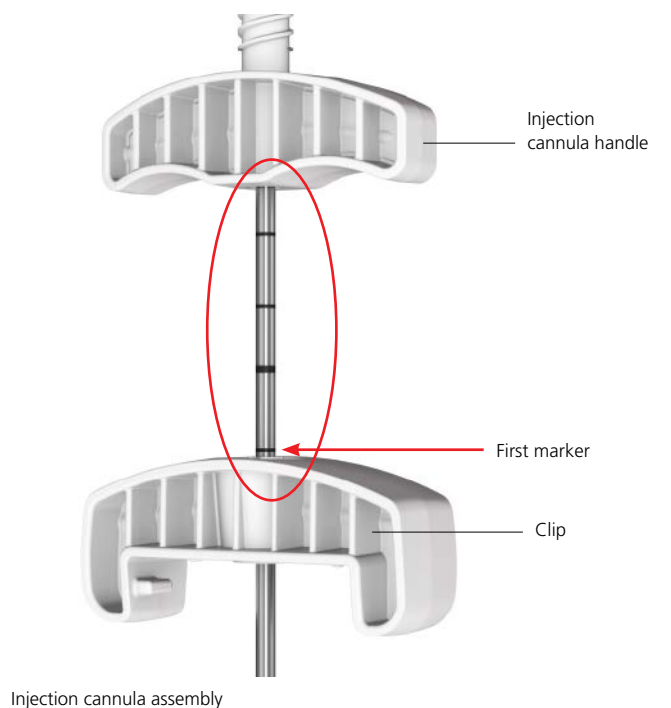
03.804.520S Access Kit, 10 Gauge,
Bevel Tip/Side Opening, Sterile

Follow the manufacturer's recommendations for PMMA use in the vertebral body.

The injection needle assembly consists of an injection needle and a plastic clip that slides along the length of the injection needle.

Before inserting the injection needle into the working sleeve, slide the plastic clip along the injection needle until all four markers are visible between the injection needle handle and the clip. The first marker represents the position of the injection needle where it is flush with the distal end of the working sleeve.

- With the first marker visible, insert the injection needle through the working sleeve and, while firmly holding the working sleeve handle, turn the clip clockwise to lock it to the working sleeve.



Connect a PMMA delivery system via the Luer lock.

Under lateral fluoroscopy, slowly advance the injection needle into the vertebral body to the position where cement injection is desired. The markers are 10 mm apart.

Notes:

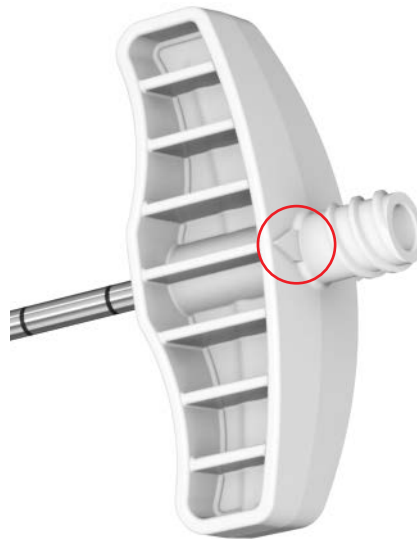
- **Hold the injection needle while connecting and disconnecting the PMMA delivery system to prevent the injection needle from moving.**
- **When using the side-opening injection needle, the second marker represents the position where the opening of the side opening injection needle is fully deployed beyond the working sleeve. This second marker is darker than the other markers.**



- Under lateral fluoroscopy, inject PMMA cement. The injection needle can be repositioned axially as desired during cement injection. The PMMA should be contained within the vertebral body.

Notes:

- When using the side-opening needle, the direction of the PMMA flow can be changed by orienting the handle of the side-opening needle to correspond to the direction of PMMA cement flow. The arrow on the handle of the side-opening needle corresponds to the side of the opening.
- If using a bilateral approach, both sides should be filled simultaneously and incrementally. It is important to see the filling behavior of both needles. Once the filling of one side is accomplished, the lateral view of the opposite side is hidden by the cement, which makes monitoring the flow more difficult.

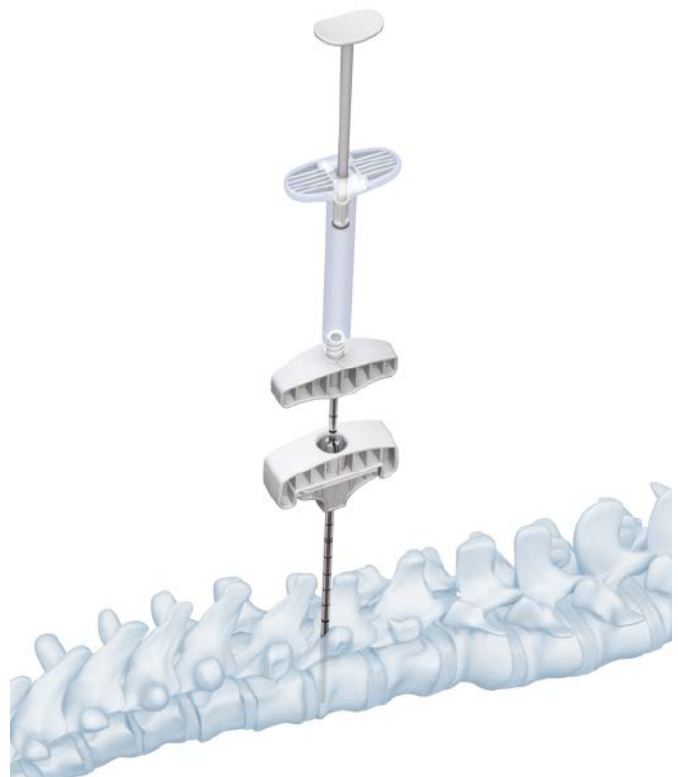


- Warning:** Closely monitor the PMMA injection under fluoroscopy to reduce the risk of cement leakage. Severe leakage can cause death or paralysis. If cement leakage is observed during the procedure STOP cement injection and consider: waiting for the cement already injected to harden, repositioning the needle, adjusting the needle direction if using a side-opening needle, or stopping the procedure. If desired, continue cement injection slowly, and carefully evaluate for further leakage. If further leakage is observed, cease cement injection.

Once the cement has fully hardened per the manufacturer's instructions, remove the injection needle and the working sleeve.

Note: If the working sleeves are removed before the cement is sufficiently hardened, there is risk of pulling cement fibers into the muscle tissue. If this happens, cement residue should be removed from the soft tissues.

Close wound.



POSTOPERATIVE CARE

6

Postoperative Care

Place the patient in the supine position after surgery to compress the wound. Bruising may occur at the puncture sites. The patient may then be mobilized at the physician's discretion.

INSTRUMENTS

03.702.750S Cavity Creation Instrument
10 mm, Sterile

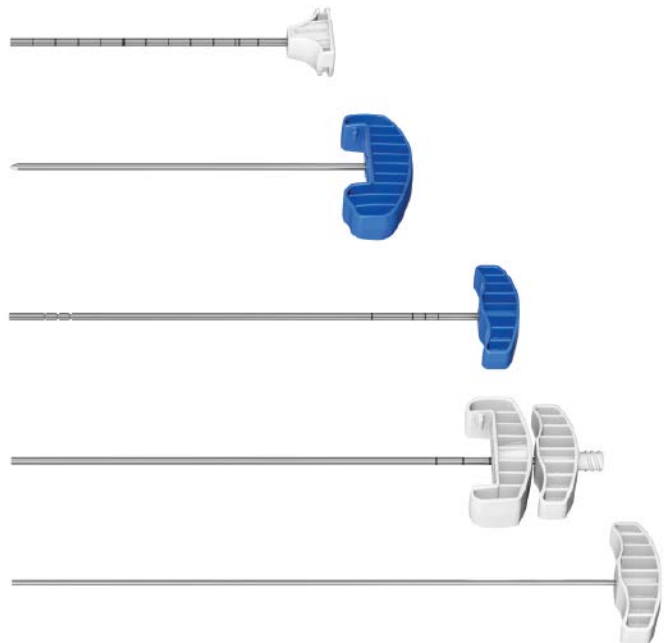


03.702.751S Cavity Creation Instrument
15 mm, Sterile



03.804.517S Access Kit, 10 Gauge,
Diamond Tip/End Opening, Sterile

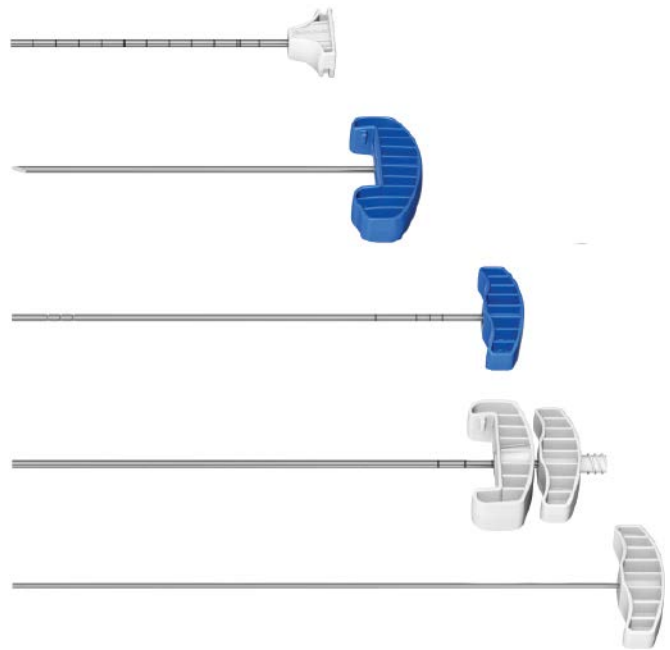
- Contains:
- 1 Working Sleeve
 - 1 Trocar Diamond Tip
 - 1 Plunger (not used with Cavity Creation Instrument)
 - 1 Injection Needle, End Opening with Clip
 - 1 Stylet



03.804.518S Access Kit, 10 Gauge,
Bevel Tip/End Opening, Sterile

Contains:

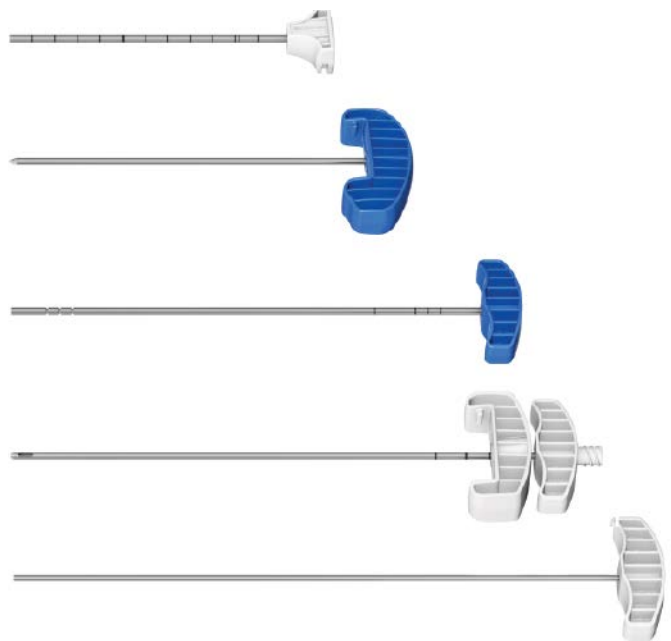
- 1 Working Sleeve
- 1 Trocar Bevel Tip
- 1 Plunger (not used with Cavity Creation Instrument)
- 1 Injection needle, End Opening with Clip
- 1 Stylet



03.804.519S Access Kit, 10 Gauge,
Diamond Tip/Side Opening, Sterile

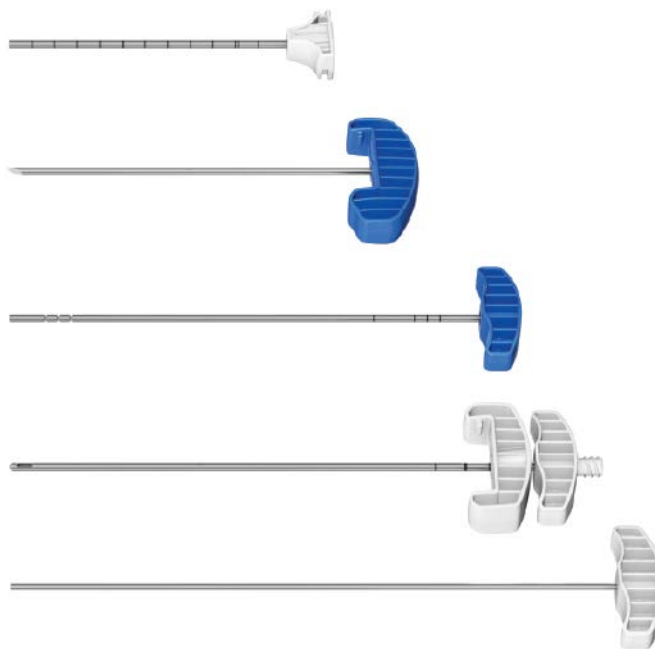
Contains:

- 1 Working Sleeve
- 1 Trocar Diamond Tip
- 1 Plunger (not used with Cavity Creation Instrument)
- 1 Injection Needle, Side Opening with Clip
- 1 Stylet



03.804.520S Access Kit, 10 Gauge,
Bevel Tip/Side Opening, Sterile

- Contains:
 1 Working Sleeve
 1 Trocar Bevel Tip
 1 Plunger (not used with Cavity Creation Instrument)
 1 Injection Needle, Side Opening with Clip
 1 Stylet



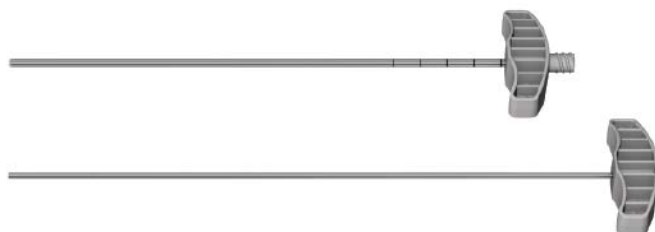
03.804.521S Access Drill, 10G, Sterile

- Contains:
 1 Drill



03.804.522S Biopsy Kit, 10G, Sterile

- Contains:
 1 Biopsy Needle
 1 Stylet



Limited Warranty and Disclaimer: DePuy Synthes Spine products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

To order in the U.S. call, Johnson & Johnson Health Care Systems Inc. Customer Support Services at 800-255-2500.

Not all products are currently available in all markets.

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