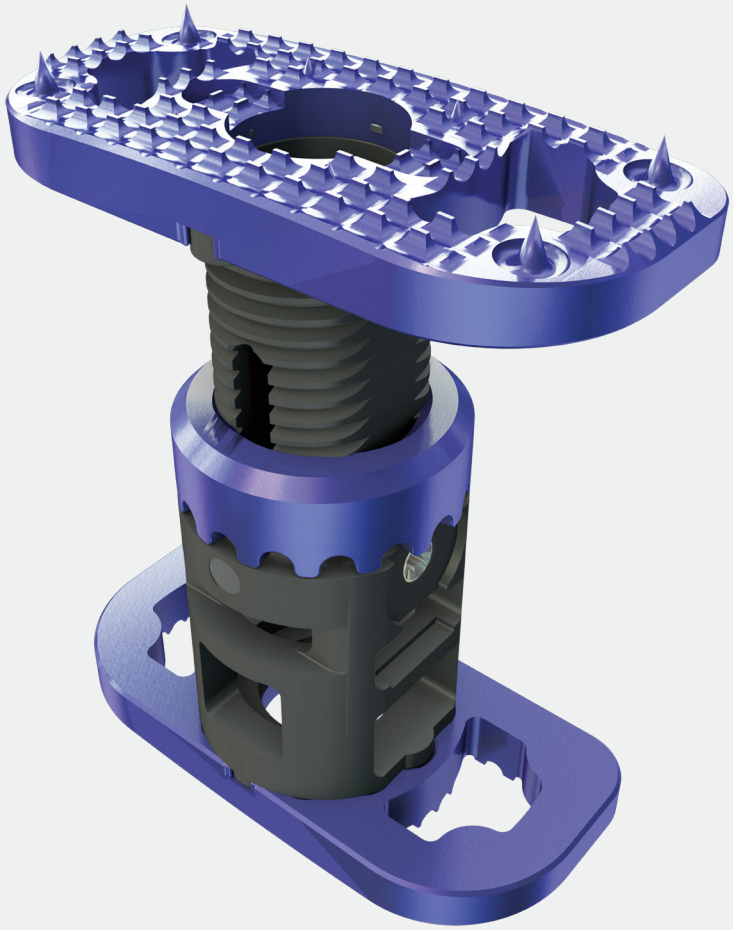


XCore 2

Technique guide

NuVasive

This document is intended exclusively for physicians.

This document contains general information on the products and/ or procedures discussed herein and should not be considered as medical advice or recommendations regarding a specific patient or their medical condition.

This surgical technique guide offers guidance but is not a substitute for the comprehensive training surgeons have received. As with any such technique guide, each surgeon should use his or her own independent medical judgment to consider the particular needs of the patient and make appropriate clinical decisions as required. A successful result is not always achieved in every surgical case.

As with all surgical procedures and permanent implants, there are risks and considerations associated with surgery and the implant, including the use of the X-CORE 2 VBR device. It may not be appropriate for all patients and all patients may not benefit.

It is the surgeon's responsibility to discuss all relevant risks with the patient prior to surgery.

All non-sterile devices must be cleaned and sterilized before use. Multi-component instrument assemblies must be disassembled prior to cleaning.

This surgical technique guide provides information supplemental to information provided in the individual system instructions for use (IFU) regarding the products referenced herein.

For a complete list of intended uses, indications, device description, contraindications, warnings, and precautions. Please refer to the Instructions for Use (IFU) of each device at www.nuvasive.com/eifu. A summary is also available in the back of this technique guide.

Contents

XCore 2 VBR overview

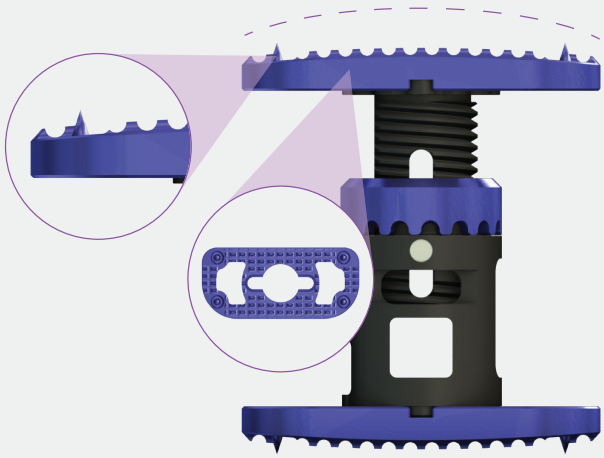
Biomechanical strength

XLIF endcaps—increased resistance to subsidence

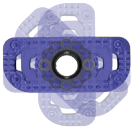
The second generation XCore 2 VBR has XLIF style endcaps that are specifically designed to span the ring apophysis. Data shows that XLIF endcaps of the XCore 2 VBR provide an increased resistance to subsidence as compared to cylindrical VBRs.[1,2]

The XCore 2 VBR endcaps are contoured to match endplate anatomy and equipped with anti-migration features that are designed to provide increased fixation.

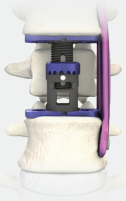
The entire construct has been optimized to provide a significant increase in graft aperture, both throughout the core, and endcaps, to aid in maximized fusion rate.



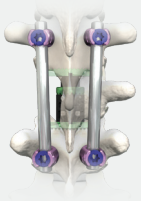
Versatile, all-approach cage



The XCore 2 VBR is designed to be a versatile and advanced all-approach, expandable corpectomy VBR. The XCore 2 VBR system allows surgeons to utilize novel XLIF style endcaps from any approach. With the core's unique flower pattern attachment feature, endcaps can be attached in up to 12 different insertion angles, allowing surgeons to maximize the implant footprint without being limited by the approach to the spine being utilized.



XLIF approach



Posterior approach

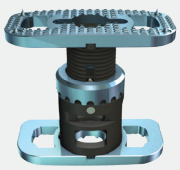
Anterior approach

Customizable to match patient anatomy

Three different core diameters and 75+ endcap options (both XLIF style and round endcaps in varying lengths, diameters, and lordotic options) allow surgeons to customize the implant to match patient anatomy.

16 mm

18 mm



22 mm

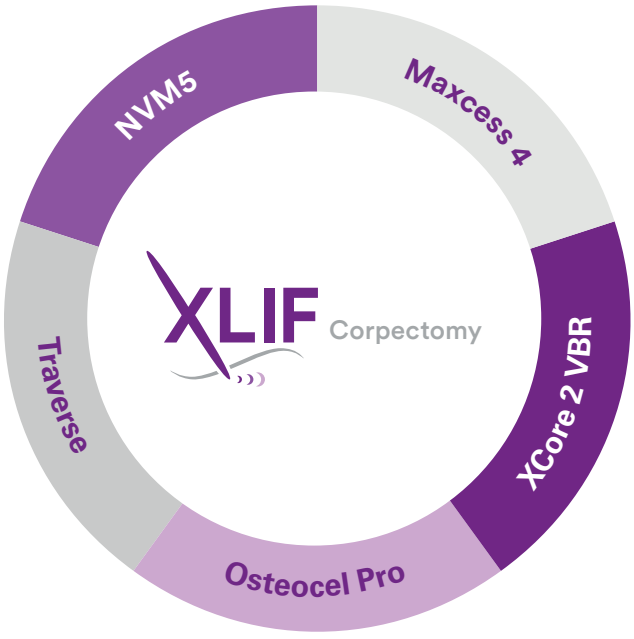
Minimally disruptive

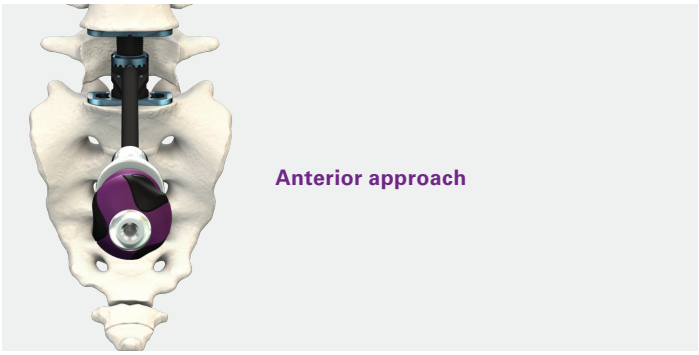
The XCore 2 VBR system provides a zero profile inserter/expander in one instrument, decreasing the number of surgical steps.

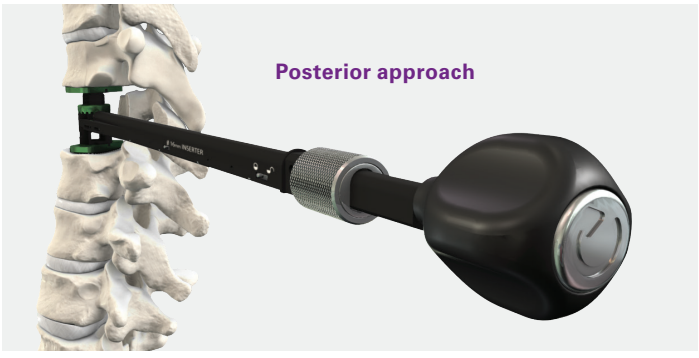
- Zero profile arms engage onto core, minimizing anatomical disruption, maximizing the size of the VBR that can be placed, and enabling the VBR to be placed via multiple approaches.
- Single-step inserter/expander decreases surgical steps.
- Inserter provides increased distraction compared to similar devices on the market.

The XCore 2 VBR functions seamlessly within the XLIF Corpectomy portfolio of products, making the implant part of a unique procedural solution for tumor and trauma applications.

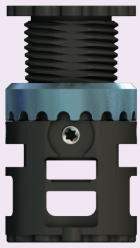
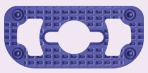
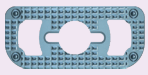
Designed to match patient anatomy, the modular XCore 2 VBR provides three core diameters (16, 18 and 22 mm) and 75+ options for both XLIF style and round endcaps. The XCore 2 VBR system allows surgeons to customize each implant to the anatomy of the patient. Additionally, the design of the implant and instrumentation enables surgeons to treat patients with the XCore 2 VBR via multiple surgical approaches. Consideration of the level being treated and desired surgical goals will determine the surgical approach used.







XCore 2 VBR endcap options

16 mm diameter core		18 mm diameter core		22 mm diameter core	
					
Endcaps for Ø 16 mm core		Endcaps for Ø 18 mm core		Endcaps for Ø 22 mm core	
					
XLIF endcaps • 16x30 mm • 16x40 mm **Lordosis** • -4°, 0°, 4°	**Round endcaps** • 16 mm • 18 mm **Lordosis** • 0°, 4°	**XLIF endcaps** • 18x30 mm • 18x40 mm • 18x50 mm **Lordosis** • -4°, 0°, 4° **Additional XLIF endcaps** • 22x30 mm • 22x40 mm • 22x50 mm • 22x60 mm **Lordosis** • 0°, 4°, 8°, 12°	**Round endcaps** • 18 mm • 22 mm • 26 mm **Lordosis** • 0°, 4°, 8°	**XLIF endcaps** • 22x40 mm • 22x50 mm • 22x60 mm **Lordosis** • 0°, 4°, 8°, 12°	**Round endcaps** • 22 mm • 26 mm • 30 mm **Lordosis** • 0°, 4°, 8°, 12°

Equipment requirements

- Options:
  - XCore 2 VBR 16 mm implant/instrument tray
  - XCore 2 VBR 18 mm implant/instrument tray
  - XCore 2 VBR 22 mm implant/instrument tray
- XLIF Corpectomy instrument tray
- Maxcess 4 access system
- Maxcess 4 articulating arm
- Maxcess 4 disposables
- XLIF instruments
- NVM5 system and disposables
- Fixation options such as Traverse lateral plate
- Biologics options such as Osteocel Pro

For a complete list of intended uses, indications, device description, contraindications, warnings and precautions, please refer to the IFU in the back of this technique guide.

XLIF approach

Step 1

Sizer

After achieving access to the target anatomy, perform the corpectomy. When taking a lateral approach to the spine, reference the XLIF Corpectomy surgical technique (document #9511977 A).

Once the corpectomy at the desired level has been completed, it is time to determine the appropriate core diameter, endcap size and core height.

Measuring core diameter

After confirming all desired bony material has been resected, utilize the core trial to determine the appropriate core diameter: 16, 18 or 22 mm core diameters are available *(Fig. 1)*.

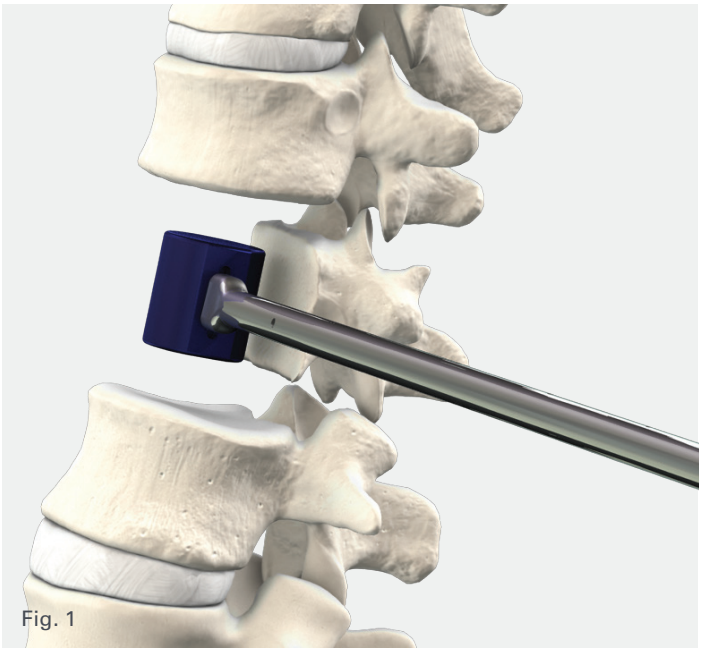


Fig. 1

Measuring endcap size

The XLIF style endcaps of the XCore 2 VBR are designed to span the ring apophysis of the vertebral body to provide maximum support. It is important that the disc material is fully evacuated to properly place the implant. Utilize endcap trials *(Fig. 2)* to determine appropriate length. Endcaps in 30–60 mm lengths are available, depending on core diameter selection.

Fig. 2

Sizer (cont.)

Measuring core height

Use the XCore 2 VBR height caliper to measure the defect height. Place caliper tips within the ipsilateral side of the void, confirming each tip is seated flush onto the superior and inferior endplates *(Fig. 3)*.

Under no distraction, obtain the reading of the defect height, as indicated on either the top or side of the measuring device.

If additional distraction is required, utilize the XCore 2 VBR distractor to do so *(Fig. 4)*. This instrument will not provide height reading but will help to distract the disc space.

Fig. 3

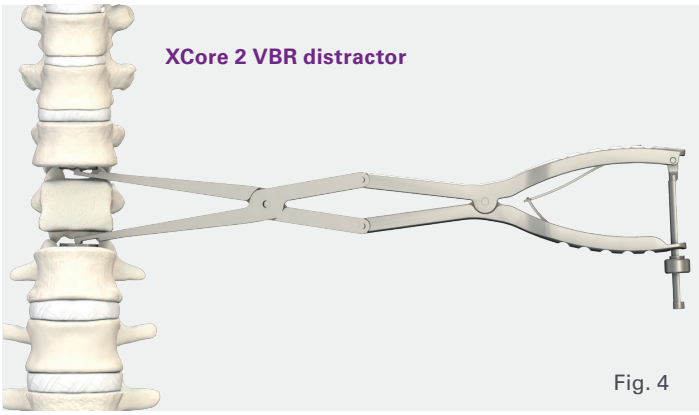


Fig. 4

Step 2

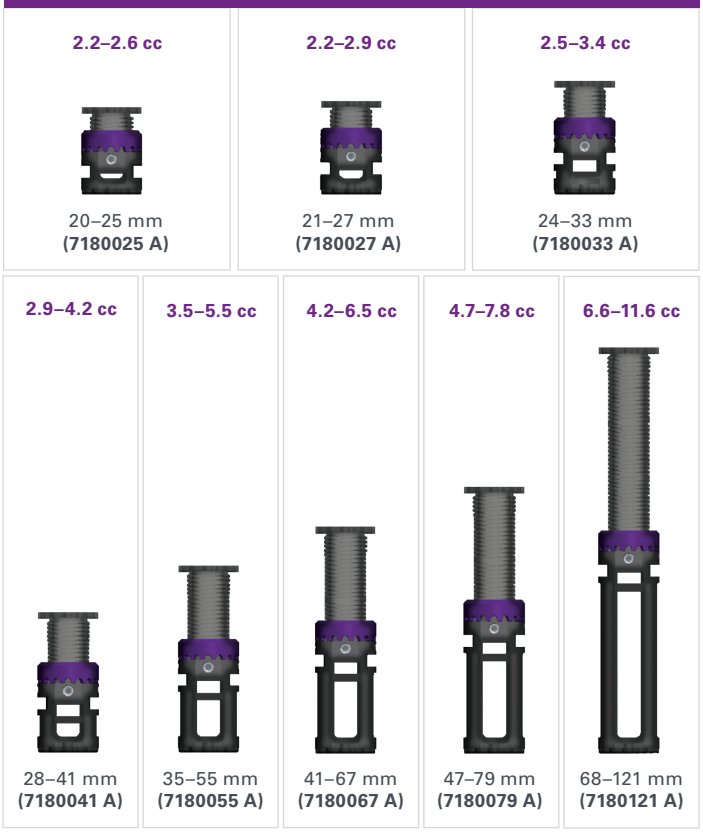
Implant construction

Once core diameter, endcap sizes and overall construct height have been determined, utilize the XCore 2 VBR sizing chart to select the appropriate core height.

Note: *Each endcap and lordotic option adds differing amounts of height per endcap. These additions must be taken into account when selecting the core.*

Ø 18 mm endcap height reference	
Description	**Added height per endcap**
Round, 0°	2.5 mm
Round, 4°	3.5 mm
Round, 8°	4.5 mm
XLIF, 0°	3.5 mm
XLIF, +/-4°	4.5 mm
XLIF, 8°	5.5 mm
XLIF, 12°	6.5 mm

Ø 18 mm core reference



**NuVasive offers Osteocel Pro as an allograft cellular bone matrix graft material which can be packed into the implant.*

Implant construction (cont.)

It is recommended to use the loading block when compiling the XCore 2 VBR.

To load the core onto the inserter, place the core into the appropriate size loading block *(Fig. 5)*.

Orient the core into its place in the loading block with the core set screw facing upward. Line up the spinning sleeve of the core with the indicated grooves.

Prior to engaging the core, verify that the inserter is in the "unlock" position. To do so, turn the silver, knurled thumbwheel on the inserter counterclockwise, confirming that the location of the pin on the inserter shaft is in the "unlock" position within the lock/unlock indicator on the side of the inserter *(Figs. 6, 6a)*.

Slide the inserter down onto the core so that the zero profile arms slide down and fully into place within the slots on the side of the core *(Figs. 7, 7a)*.

To lock the core onto the inserter, spin the silver, knurled thumbwheel clockwise.

While spinning the thumbwheel, monitor the translation of the lock/unlock indicator on the side of the inserter. Once the pin translates to the "lock" position, the inserter is fully locked onto the core.

Note: *No force is required to further lock the core onto the inserter. Once the knurled thumbwheel bottoms out, and the pin on the shaft of the inserter has translated to the "lock" position, stop spinning the thumbwheel. This requires only a two-finger grip.*

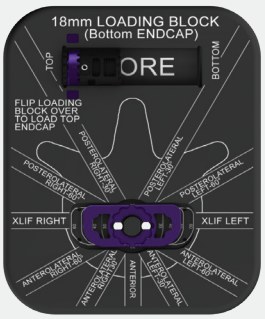


Fig. 5

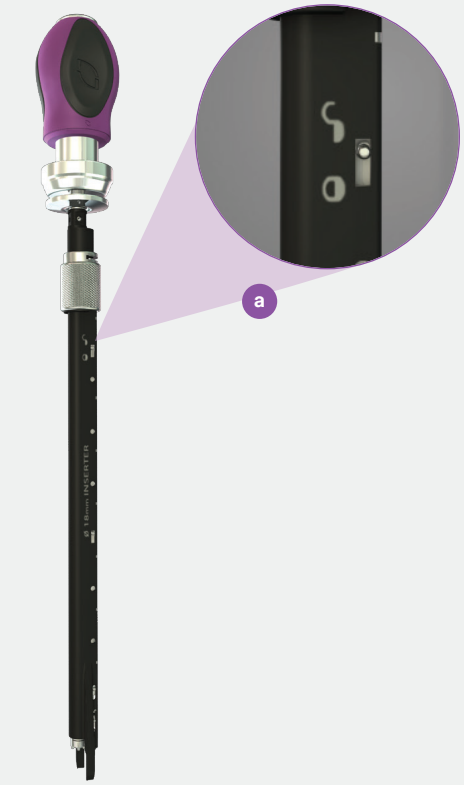


Fig. 6

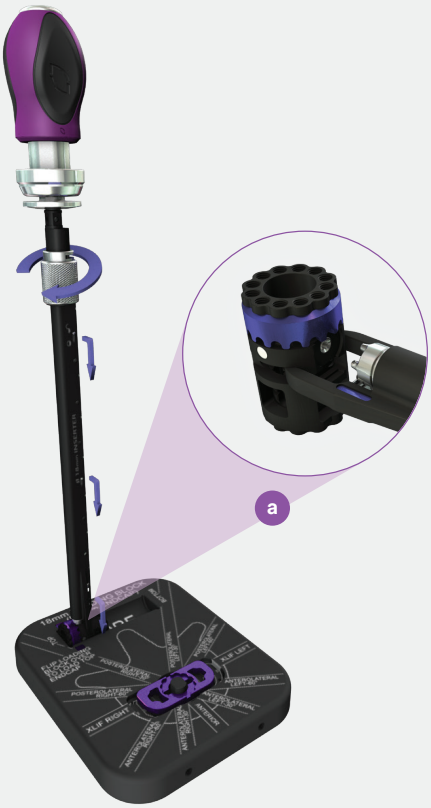


Fig. 7

Implant construction (cont.)

With the core attached onto the inserter, orient the inserter shaft against the loading block imagery according to the surgical approach desired, and place the core down onto the bottom endcap that has been placed within the loading block *(Fig. 8)*.

The endcap within the loading block should be oriented with the core mating feature of the endcap facing upward, and the spikes/top of the endcap lying flush down into the loading block.

Using the short endcap lock screw driver and two endcap lock screws per endcap, lock the endcaps onto the core. The endcap lock screw driver will break away when the endcaps are fully tightened *(Fig. 9)*.

Flip the loading block over and repeat the process to attach the top endcap, confirming that both endcaps are oriented in the same direction upon final construction.

Spin the purple teardrop handle of the inserter clockwise to expand and counterclockwise to compress the core, verifying appropriate engagement of the inserter onto the core *(Fig. 10)*.

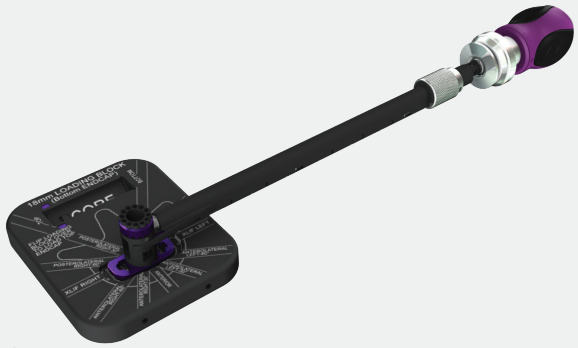


Fig. 8

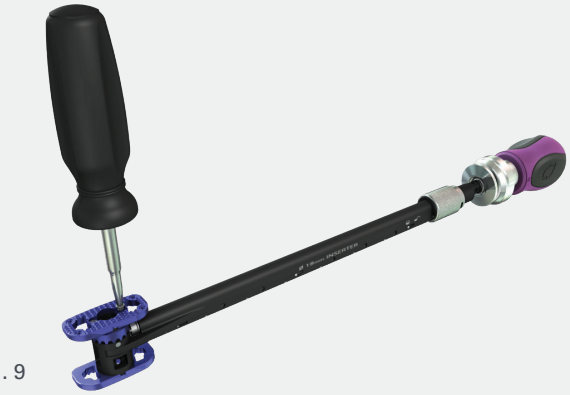


Fig. 9

Fig. 10

Step 3

Implant insertion

Insert the assembled construct in its compressed position into the prepared space *(Fig. 12)*.

Note: *The implant can be placed with the spinning sleeve of the core right side up or upside down, as long as the rounds and/or lordosis of the endcaps are oriented anterior.*

Fig. 12

Step 4

Implant expansion

Spin the teardrop handle clockwise to expand the implant *(Fig. 13)*.

Monitor implant expansion under fluoroscopy *(Fig. 13a)* and note when the implant has reached full expansion. This also may be monitored by following the translation of the threads of the inner core as they advance upward through the central aperture of the outer core. Once all of the threads have advanced to the top of the central aperture, the implant has likely reached maximum expansion. A positive stop will be felt when the core is fully expanded.

Fig. 13

In collapsed spaces or for increased control during implant expansion, attach the counter-torque handle onto the inserter *(Fig. 14)*.

Note: *Once the core is either in its fully compressed or fully expanded state, do not continue to rotate the teardrop handle. Over-expanding or over-compressing may result in implant stripping.*

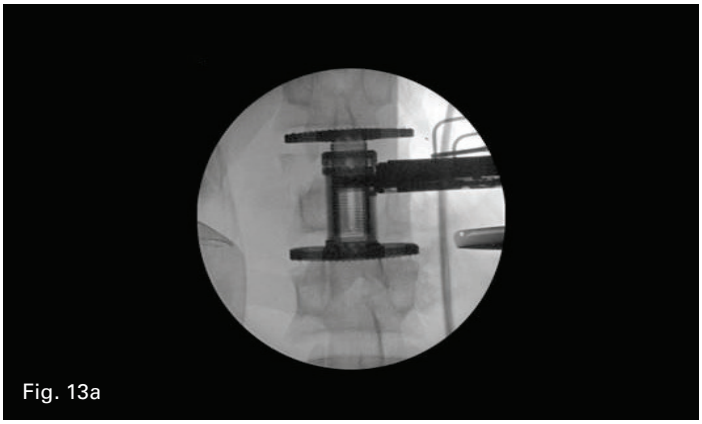


Fig. 13a

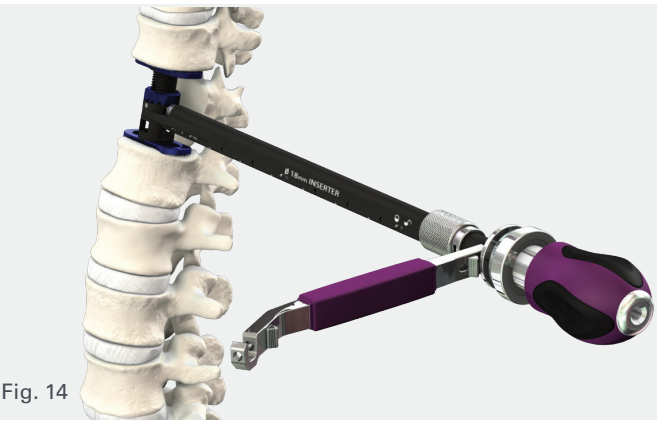


Fig. 14

Step 5

Inserter release

Once the desired expansion is reached, turn the silver, knurled thumbwheel counterclockwise to release the inserter from the core, and pull the inserter straight off the core *(Fig. 15)*.

Step 6

Final tightening

Upon final confirmation that implant is at desired height, use the core lock screw driver to lock the construct into place. Engage the core lock screw driver onto the core set screw and rotate clockwise until it breaks away. It will torque off at 10 in-lb *(Figs. 16, 17)*.

Step 7

Fixation

Select and place desired fixation system, such as the Traverse lateral plate *(Fig. 18–19a)*.

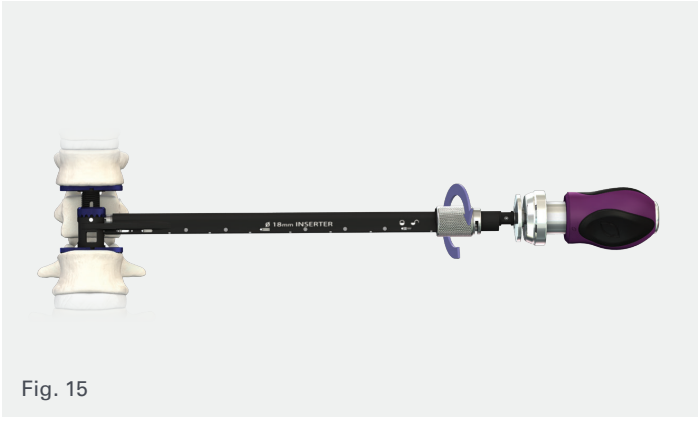


Fig. 15

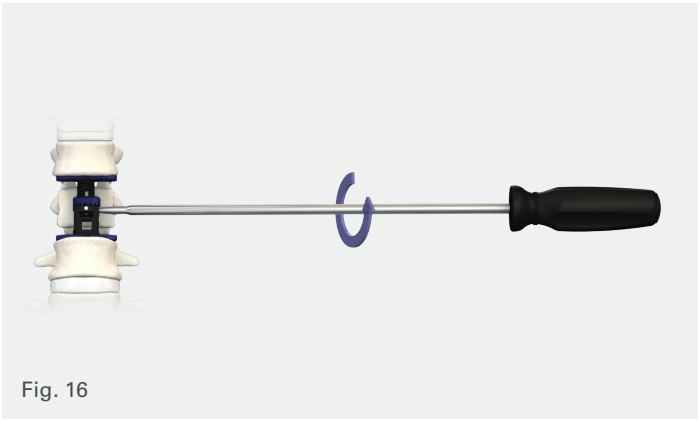


Fig. 16

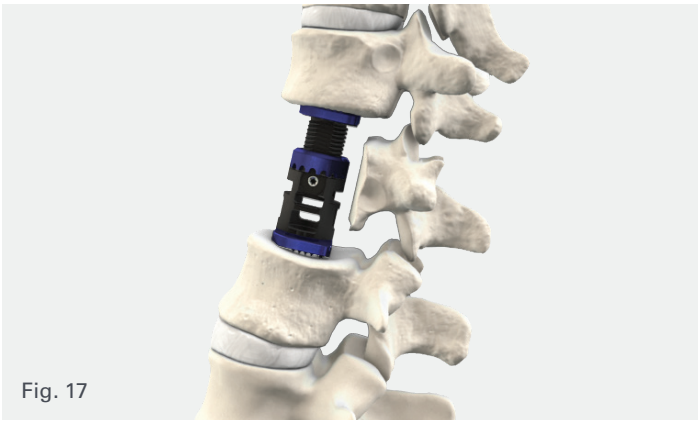


Fig. 17

Fig. 18

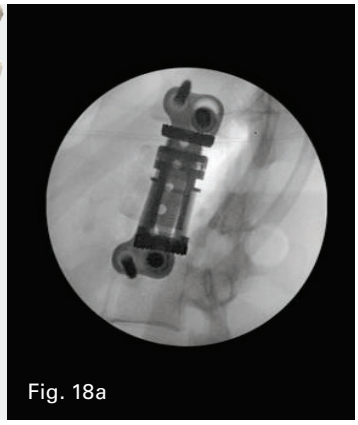


Fig. 18a

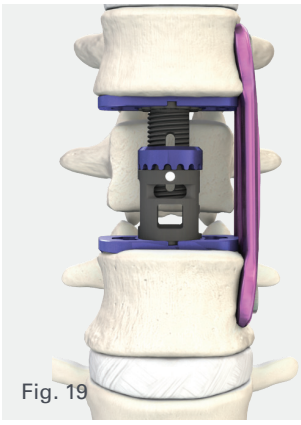


Fig. 19

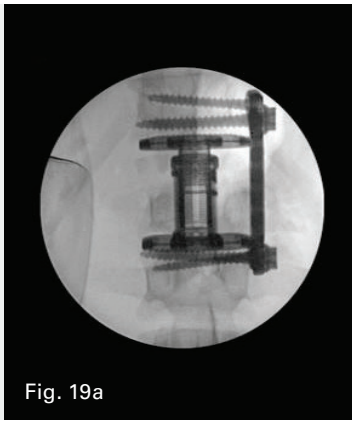


Fig. 19a

Step 8

Construct removal

Should implant removal be required, unlock the set screw with the set screw driver, and turn the set screw approximately half turn counterclockwise *(Fig. 20)*.

Step 9

Retract the core

Prior to engaging the core, confirm the inserter is in the "unlock" position by turning the silver, knurled thumbwheel on the inserter all the way counterclockwise to confirm it is fully unlocked. Again, this can be confirmed by the lock/unlock indicator on the side of the inserter shaft.

Slide the inserter onto the core so that the zero profile arms slide down and fully into place within the slots on the side of the core, and the inserter engages onto the face of the core set screw.

Turn the silver, knurled thumbwheel clockwise to fully lock the core onto the inserter. Turn the purple teardrop handle counterclockwise to collapse the VBR and carefully remove the implant *(Figs. 21, 22)*.

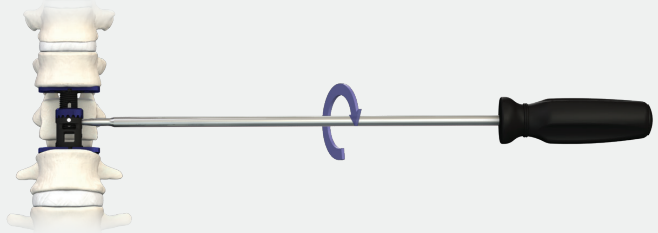


Fig. 20

Fig. 21

Fig. 22

Posterior approach

Step 1

Sizing

Once the corpectomy at the desired level has been completed, it is time to determine the appropriate core diameter, endcap size and core height.

Measuring core diameter

After confirming all desired bony material has been resected, utilize the core trial to determine the appropriate core diameter: 16, 18 or 22 mm core diameters are available *(Fig. 23)*.

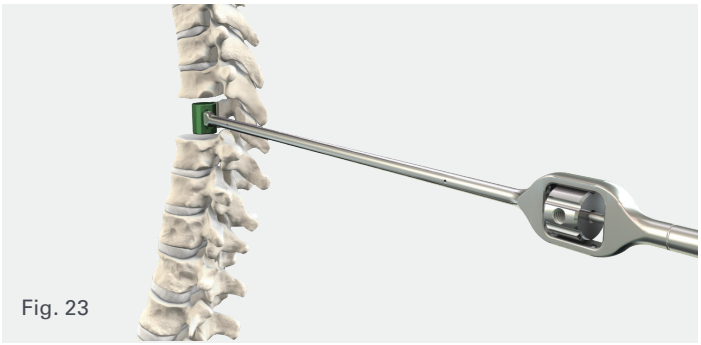


Fig. 23

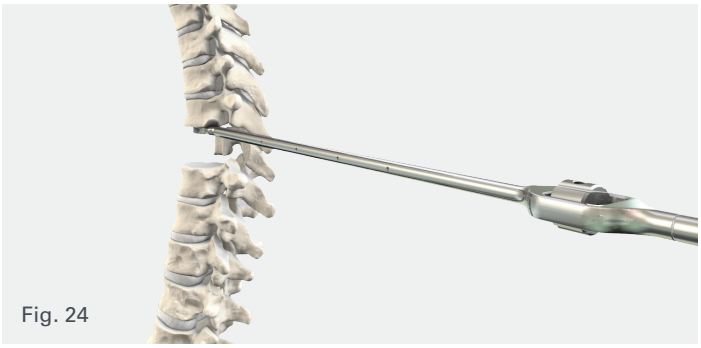


Fig. 24

Measuring endcap size

For the posterior approach, XLIF style or round endcaps may be utilized *(Fig. 24)*. The XLIF style endcaps of the XCore 2 VBR are designed to span the ring apophysis of the vertebral body to provide maximum support. It is important that the disc material is fully evacuated to properly place the implant. Once implant diameter is confirmed, utilize endcap trials to determine appropriate length or diameter endcap. Endcaps in 30–60 mm XLIF style lengths and 16–30 mm round options are available, depending on core diameter selection.

Measuring core height

Use the XCore 2 VBR height caliper to measure the defect height. Place caliper tips within the void, confirming each tip is seated flush onto the superior and inferior endplates *(Fig. 25)*.

XCore 2 VBR height caliper

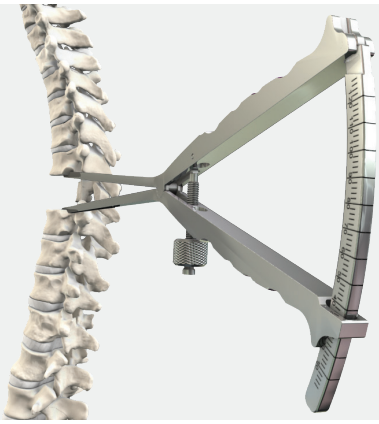


Fig. 25

Under no distraction, obtain the reading of the defect height as indicated on either the top or side of the measuring device.

If additional distraction is required, utilize the XCore 2 VBR distractor to do so *(Fig. 26)*. This instrument will not provide height reading but will help to distract the disc space.

XCore 2 VBR distractor

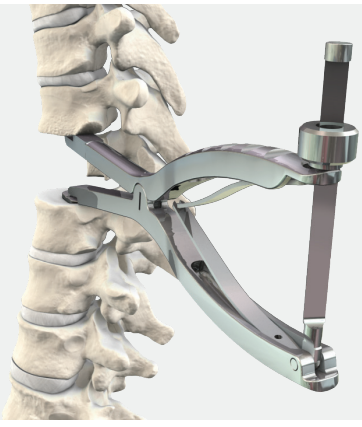


Fig. 26

Step 2

Implant construction

Once core diameter, endcap sizes and overall construct height have been determined, utilize the XCore 2 VBR sizing chart to select the appropriate core height.

Note: *Each endcap and lordotic option adds differing amounts of height per endcap. These additions must be taken into account when selecting the core.*

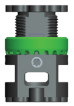
Ø 16 mm endcap height reference	
Description	**Added height per endcap**
Round, 0°	2.5 mm
Round, +/-4°	3.5 mm
XLIF, 0°	3.5 mm
XLIF, +/-4°	4.5 mm

Ø 16 mm core reference

1.2–1.6 cc

16–22 mm
(7160022)

1.3–1.7 cc



18–25 mm
(7160025)

1.6–2.3 cc

23–35 mm
(7160035)

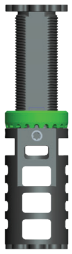
1.8–2.1 cc

26–41 mm
(7160041)

2.1–3.3 cc

30–49 mm
(7160049)

2.5–4.2 cc



37–63 mm
(7180067)

2.9–4.8 cc

44–75 mm
(7160063)

**NuVasive offers Osteocel Pro as a graft material which can be packed into the implant.*

Implant construction (cont.)

It is recommended to use the loading block when compiling the XCore 2 VBR.

To load the core onto the inserter, place the core into the appropriate size loading block *(Fig. 27)*.

Orient the core into its place in the loading block with the core set screw facing upward. Line up the spinning sleeve of the core with the indicated grooves.

Prior to engaging the core, verify that the inserter is in the "unlock" position. To do so, turn the silver, knurled thumbwheel on the inserter counterclockwise, confirming that the location of the pin on the inserter shaft is in the "unlock" position within the lock/unlock indicator on the side of the inserter *(Figs. 28, 28a)*.

Slide the inserter down onto the core so that the zero profile arms slide down and fully into place within the slots on the side of the core *(Figs. 29, 29a)*.

To lock the core onto the inserter, spin the silver, knurled thumbwheel clockwise.

While spinning the thumbwheel, monitor the translation of the lock/unlock indicator on the side of the inserter. Once the pin translates to the "lock" position, the inserter is fully locked onto the core.

Note: *No force is required to further lock the core onto the inserter. Once the knurled thumbwheel bottoms out, and the pin on the shaft of the inserter has translated to the "lock" position, stop spinning the thumbwheel. This requires only a two-finger grip.*

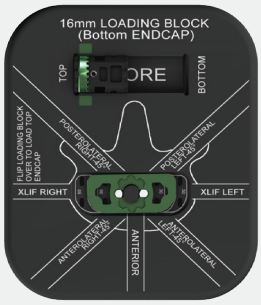


Fig. 27

Fig. 28

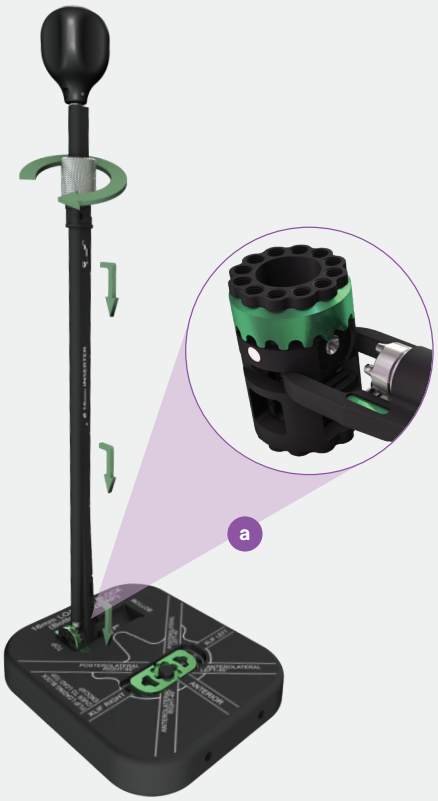


Fig. 29

Implant construction (cont.)

With the core attached onto the inserter, orient the inserter shaft against the loading block imagery according to the surgical approach desired, and drop the core down onto the bottom endcap that has been placed within the loading block *(Fig. 30)*.

The endcap within the loading block should be oriented with the core mating feature of the endcap facing upward, and the spikes/top of the endcap lying flush down into the loading block.

Note: *The flower pattern on the XCore 2 VBR core allows for endcaps to be attached in up to 12 different insertion angles for the 18 and 22 mm cores. Eight angles are available for the 16 mm core. Endcaps may be attached in 30° increments on the 18 and 22 mm cores, and in 45° increments for the 16 mm core. These options allow for either XLIF style endcaps or varying round endcaps to be utilized via multiple approaches.*

Using the short endcap lock screw driver and endcap lock screws, lock the top endcap onto the core. The endcap lock screw driver will break away when the endcaps are fully tightened *(Fig. 31)*.

Flip the loading block over and repeat the process to attach the top endcap, confirming that both endcaps are oriented in the same direction upon final construction.

Spin the teardrop handle of the inserter clockwise to expand, and counterclockwise to compress the core, verifying appropriate engagement of the inserter onto the core *(Figs. 32, 32a)*.

Fig. 30


Fig. 31

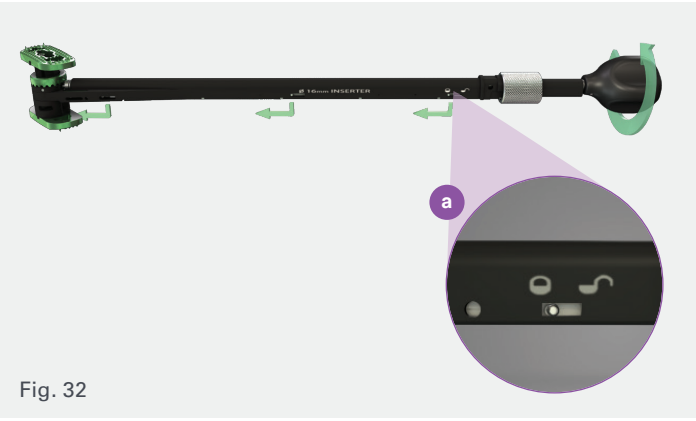


Fig. 32

Step 3

Implant insertion

Insert the assembled construct in its compressed position into the prepared space *(Fig. 34)*.

Note: *The implant can be placed with the spinning sleeve of the core right side up or upside down, as long as the rounds and/or lordosis of the XLIF endcaps are oriented anterior.*

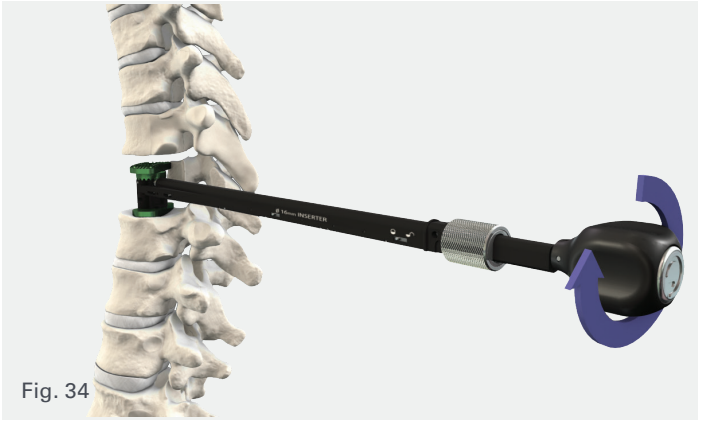


Fig. 34

Step 4

Implant expansion

Spin the teardrop handle clockwise to expand the implant *(Fig. 34)*.

Monitor implant expansion under fluoroscopy and note when the implant has reached full expansion. This also may be monitored by following the translation of the threads of the inner core as they advance upward through the central aperture of the outer core. Once all of the threads have advanced to the top of the central aperture, the implant has likely reached maximum expansion. A positive stop will be felt when the core is fully expanded.

In collapsed spaces or for increased control during implant expansion, attach the counter-torque handle onto the inserter *(Fig. 35)*.

Note: *Once the core is either in its fully compressed or fully expanded state, do not continue to rotate the teardrop handle. Over-expanding or over-compressing may result in implant stripping.*

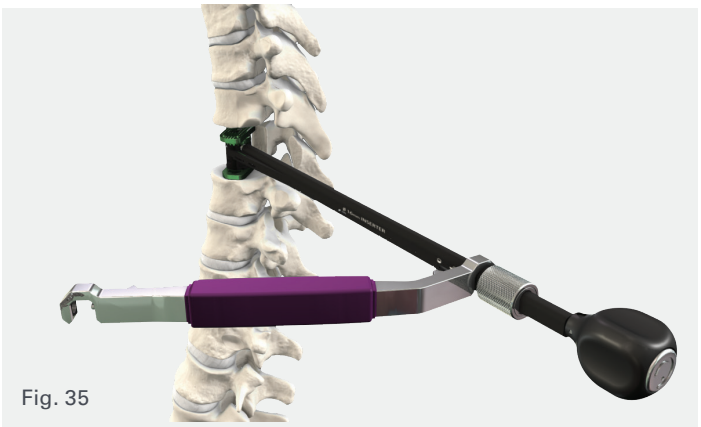


Fig. 35

Step 5

Inserter release

Once the desired expansion is reached, turn the silver, knurled thumbwheel counterclockwise to release the inserter from the core, and pull the inserter straight off the core *(Fig. 36)*.

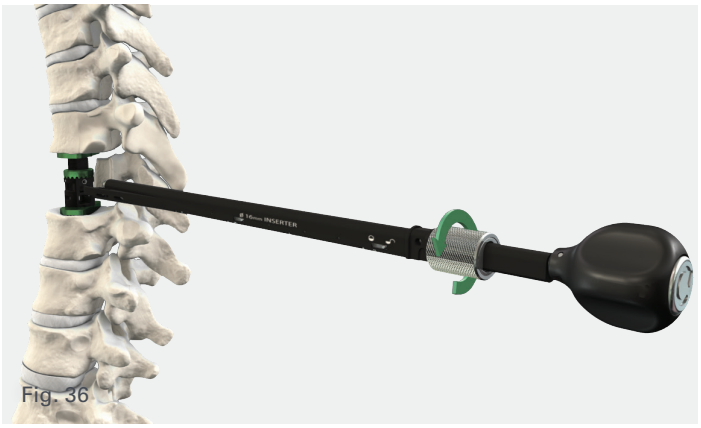


Fig. 36

For the 16 mm inserter, if required, attach the slap hammer attachment onto the end of the inserter to aid in release and removal *(Fig. 37)*.


Fig. 37

Step 6

Final tightening

Upon final confirmation that the implant is at desired height, use the core lock screw driver to lock the construct into place. Engage the core lock screw driver onto the set screw of the core and rotate clockwise until the driver breaks away. It will torque off at 10 in-lb *(Fig. 38–40)*.

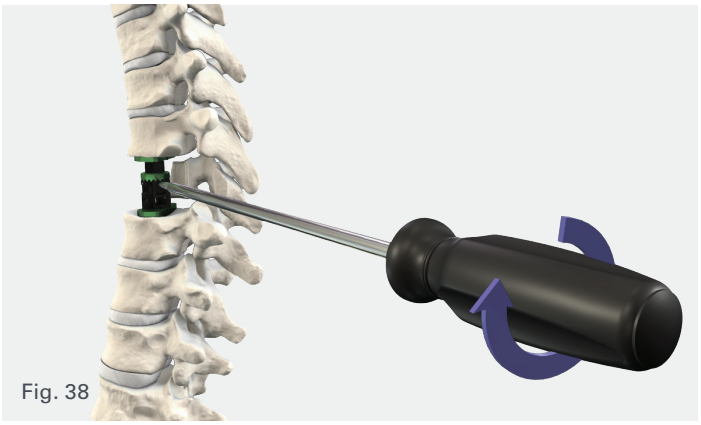


Fig. 38

Step 7

Fixation

Select and place desired fixation system, such as the supplemental internal spinal fixation systems that are cleared by the FDA for use in the thoracic and lumbar spine spinal system *(Fig. 41)*.

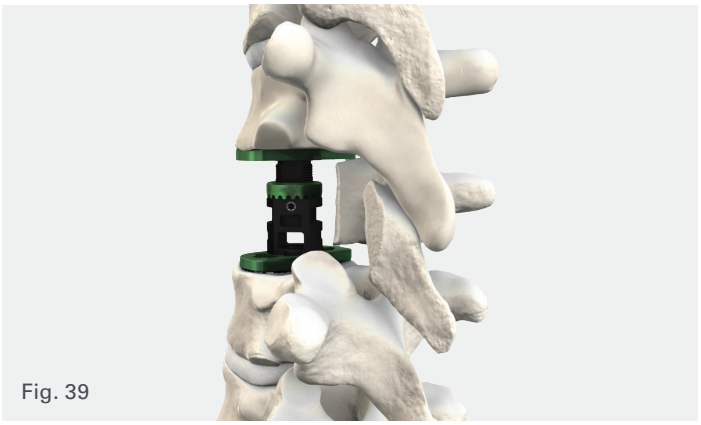


Fig. 39

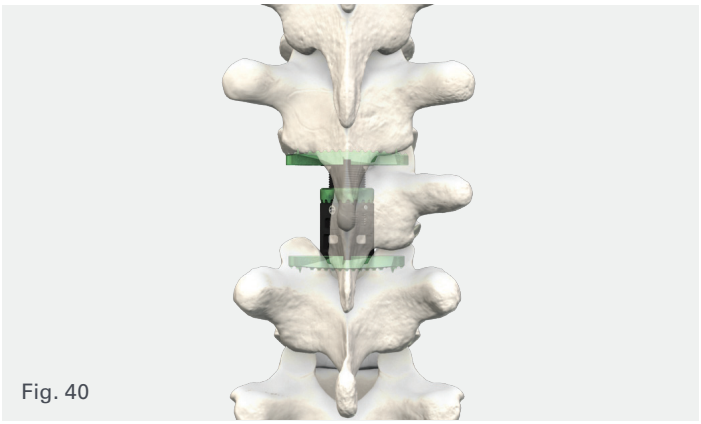


Fig. 40

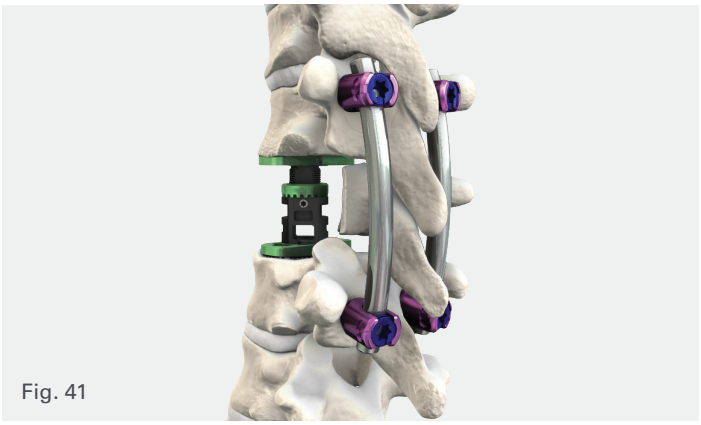


Fig. 41

Step 8

Construct removal

Should implant removal be required, unlock the set screw with the set screw driver, and turn the set screw approximately half turn counterclockwise *(Fig. 42)*.

Note: *Only a half turn is required to release the set screw. If backed out too far, the set screw may prevent the inserter from properly re-engaging the core.*

Step 9

Retract the core

Prior to engaging the core, confirm the inserter is in the "unlock" position by turning the silver, knurled thumbwheel on the inserter all the way counterclockwise to verify it is fully unlocked. Again, this can be confirmed by the lock/unlock indicator on the side of the inserter shaft.

Slide the inserter onto the core so that the zero profile arms slide down and fully into place within the slots on the side of the core, and the inserter engages onto the face of the set screw of the core *(Fig. 43)*.

Turn the silver, knurled thumbwheel clockwise to fully lock the core onto the inserter. Turn the teardrop handle counterclockwise to collapse the VBR and carefully remove the implant *(Fig. 44)*.

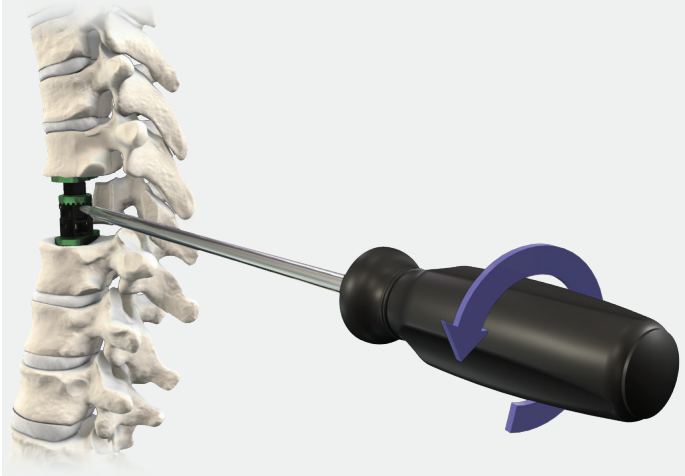


Fig. 42

Fig. 43

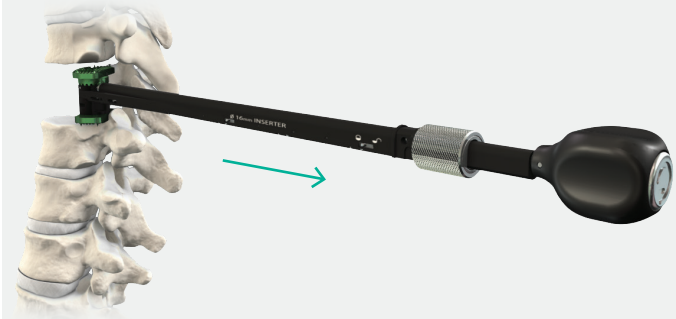


Fig. 44

Anterior approach

Step 1

Sizing

Once the corpectomy at the desired level has been completed, it is time to determine the appropriate core diameter, endcap size and core height.

Measuring core diameter

After confirming all desired bony material has been resected, utilize the core trial to determine the appropriate core diameter: 16, 18 or 22 mm core diameters are available *(Fig. 45)*.

Fig. 45

Measuring endcap size

For an anterior approach, round endcaps or even XLIF style endcaps may be utilized *(Fig. 46)*. Once implant diameter is confirmed, utilize endcap trials to determine appropriate length or diameter endcap. Endcaps in 30–60 mm XLIF style lengths and 16–30 mm round options are available, depending on core diameter selection.

Fig. 46

Measuring core height

Use the XCore 2 Expandable VBR height caliper to measure the defect height. Place caliper tips within the void opening, confirming each tip is seated flush onto the superior and inferior endplates *(Fig. 47)*.

Under no distraction, obtain the reading of the defect height as indicated on either the top or side of the measuring device.

If additional distraction is required, utilize the XCore 2 VBR distractor to do so *(Fig. 48)*. This instrument will not provide height reading but will help to distract the disc space.

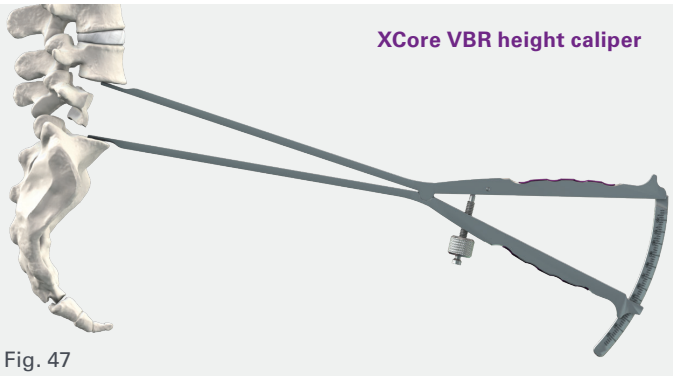


Fig. 47

Fig. 48

Step 2

Implant construction

Once core diameter, endcap sizes and overall construct height have been determined, utilize the XCore 2 VBR sizing chart to select the appropriate core height.

Note: *Each endcap and lordotic option adds differing amounts of height per endcap. These additions must be taken into account when selecting the core.*

Ø 22 mm endcap height reference	
Description	**Added height per endcap**
Round, 0°	2.5 mm
Round, 4°	3.5 mm
Round, 8°	4.5 mm
Round, 12°	5.5 mm
XLIF, 0°	3.5 mm
XLIF, +/-4°	4.5 mm
XLIF, 8°	5.5 mm
XLIF, 12°	6.5 mm

Ø 22 mm core reference

3.6–4.2 cc

20–25 mm
(7220025 A)

3.9–4.8 cc

21–27 mm
(7220027 A)

4.3–5.7 cc

24–33 mm
(7220033 A)

4.9–7.0 cc

28–41 mm
(7220041 A)

6.1–9.2 cc

35–55 mm
(7220055 A)

7.0–11.2 cc

41–67 mm
(7220067 A)

8.1–13.1 cc

47–79 mm
(7220079 A)

11.3–19.9 cc

68–121 mm
(7220121 A)

**NuVasive offers Osteocel Pro as a graft material which can be packed into the implant.*

Implant construction (cont.)

It is recommended to use the loading block when compiling the XCore 2 VBR.

To load the core onto the inserter, place core into the appropriate size loading block *(Fig. 49)*.

Orient the core into its place in the loading block with the core set screw facing upward. Line up the spinning sleeve of the core with the indicated grooves.

Prior to engaging the core, verify that the inserter is in the "unlock" position. To do so, turn the silver, knurled thumbwheel on the inserter counterclockwise, confirming that the location of the pin on the inserter shaft is in the "unlock" position within the lock/unlock indicator on the side of the inserter *(Figs. 50, 50a)*.

Slide the inserter down onto the core so that the zero profile arms slide down and fully into place within the slots on the side of the core *(Figs. 51, 51a)*.

To lock the core onto the inserter, spin the silver, knurled thumbwheel clockwise.

While spinning the thumbwheel, monitor the translation of the lock/unlock indicator on the side of the inserter. Once the pin translates to the "lock" position, the inserter is fully locked onto the core.

Note: *No force is required to further lock the core onto the inserter. Once the knurled thumbwheel bottoms out, and the pin on the shaft of the inserter has translated to the "lock" position, stop spinning the thumbwheel. This requires only a two-finger grip.*

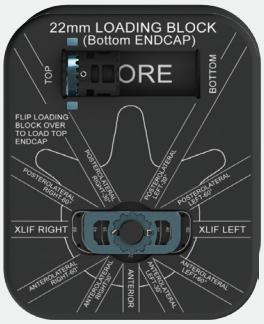


Fig. 49

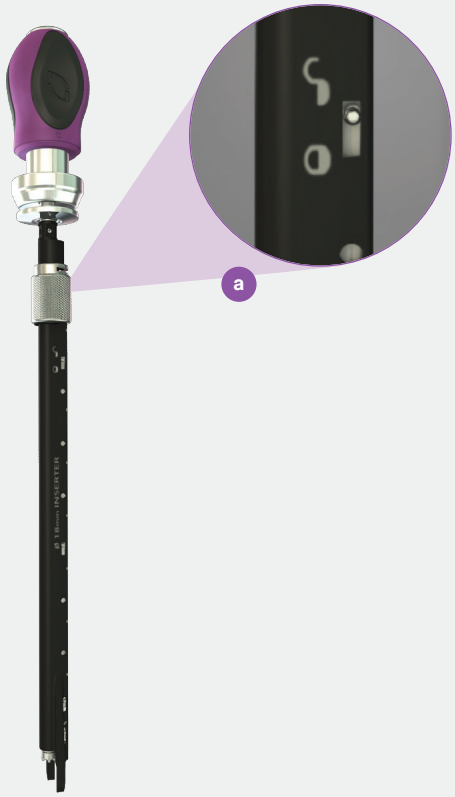


Fig. 50

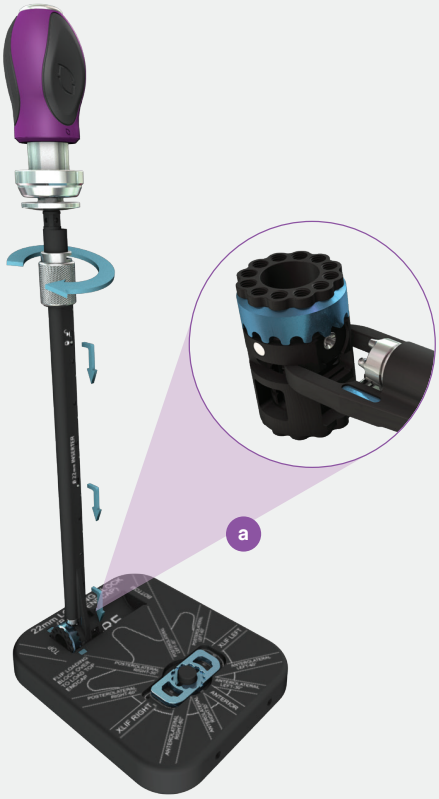


Fig. 51

Implant construction (cont.)

With the core attached onto the inserter, orient the Inserter shaft to mirror the surgical approach imagery on the loading block, and advance the core down onto the bottom endcap that has been placed within the loading block *(Fig. 52)*.

The endcap within the loading block should be oriented with the core mating feature of the endcap facing upward, and the spikes/top of the endcap lying flush down into the loading block.

Note: *The flower pattern on the XCore 2 VBR core allows for endcaps to be attached in up to 12 different insertion angles for the 18 and 22 mm cores. Eight angles are available for the 16 mm core. Endcaps may be attached in 30° increments on the 18 and 22 mm cores, and in 45° increments for the 16 mm core. These options allow for either XLIF style endcaps or varying round endcaps to be utilized in the appropriate orientation during an approach.*

Using the short endcap lock screw driver and endcap lock screws, lock the top endcap onto the core. The endcap lock screw driver will break away when the endcaps are fully tightened *(Fig. 53)*.

Flip the loading block over and repeat the process for the top endcap, confirming that both endcaps are oriented in the same direction upon final construction.

Spin the purple teardrop handle of the inserter clockwise to expand, and counterclockwise to compress the core, verifying appropriate engagement of the inserter onto the core *(Fig. 54)*.

Fig. 52

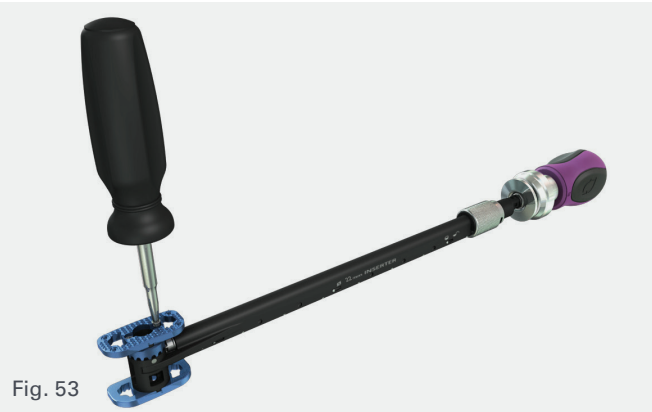


Fig. 53

Fig. 54

Step 3

Implant insertion

Insert the assembled construct in its compressed position into the prepared space *(Fig. 56)*.

Note: *The implant can be placed with the spinning sleeve of the core right side up or upside down, as long as the rounds and/or lordosis of the XLIF endcaps are oriented anterior.*

Step 4

Implant expansion

Spin the teardrop handle clockwise to expand the implant *(Fig. 57)*.

Monitor implant expansion under fluoroscopy and note when the implant has reached full expansion. This also may be monitored by following the translation of the threads of the inner core as they advance upward through the central aperture of the outer core. Once all of the threads have advanced to the top of the central aperture, the implant has likely reached maximum expansion. A positive stop will be felt when the core is fully expanded.

In collapsed spaces or for increased control during implant expansion, attach the counter-torque handle onto the inserter *(Fig. 58)*.

Note: *Once the core is either in its fully compressed or fully expanded state, do not continue to rotate the teardrop handle. Over-expanding or over-compressing may result in implant stripping.*

Fig. 56

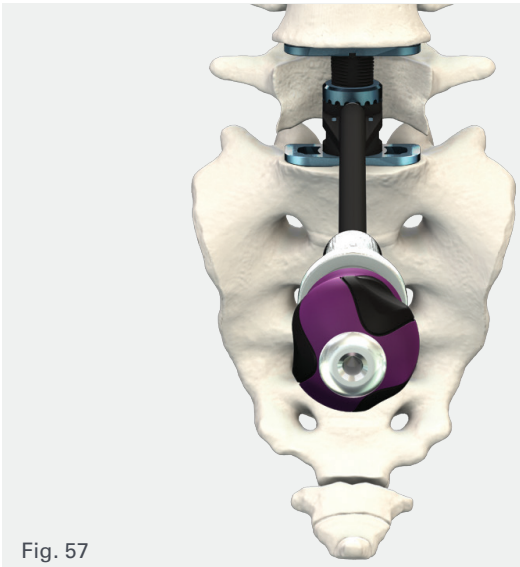


Fig. 57

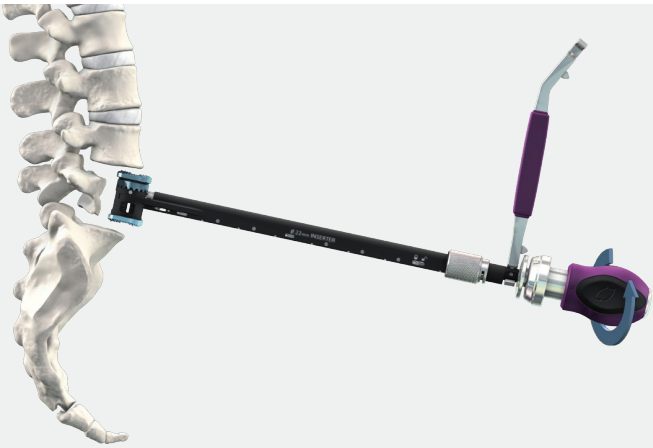


Fig. 58

Step 5

Inserter release

Once the desired expansion is reached, turn the silver, knurled thumbwheel counterclockwise to release the inserter from the core, and pull the inserter straight off the core *(Fig. 59)*.

Step 6

Final tightening

Upon final confirmation that implant is at desired height, use the core lock screw driver to lock the construct into place. Engage the core lock screw driver onto the set screw of the core and rotate clockwise until the driver breaks away. It will torque off at 10 in-lb *(Fig. 60)*.

Step 7

Fixation

After cage insertion, place supplemental spinal fixation.

Fig. 59

Fig. 60

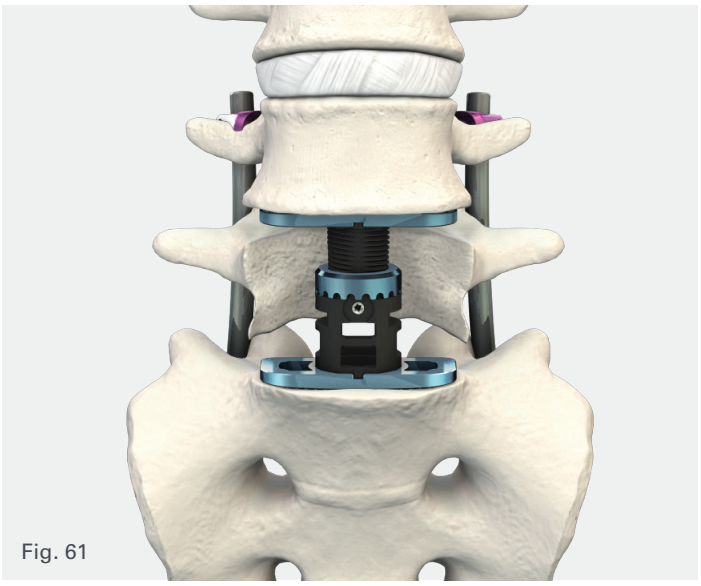


Fig. 61

Step 8

Construct removal

Should implant removal be required, unlock the set screw with the set screw driver, and turn the set screw approximately half turn counterclockwise *(Fig. 62)*.

Note: *Only a half turn is required to release the set screw. If backed out too far, the set screw may prevent the inserter from properly re-engaging the core.*

Step 9

Retract the core

Prior to engaging the core, confirm the inserter is in the "unlock" position by turning the silver, knurled thumbwheel on the inserter all the way counterclockwise to verify it is fully unlocked. Again, this can be confirmed by the lock/unlock indicator on the side of the inserter shaft.

Slide the inserter onto the core so that the zero profile arms slide down and fully into place within the slots on the side of the core, and the inserter engages onto the face of the set screw of the core.

Turn the silver, knurled thumbwheel clockwise to fully lock the core onto the inserter. Turn the purple teardrop handle counterclockwise to collapse the VBR and carefully remove the implant *(Fig. 63)*.

Fig. 62

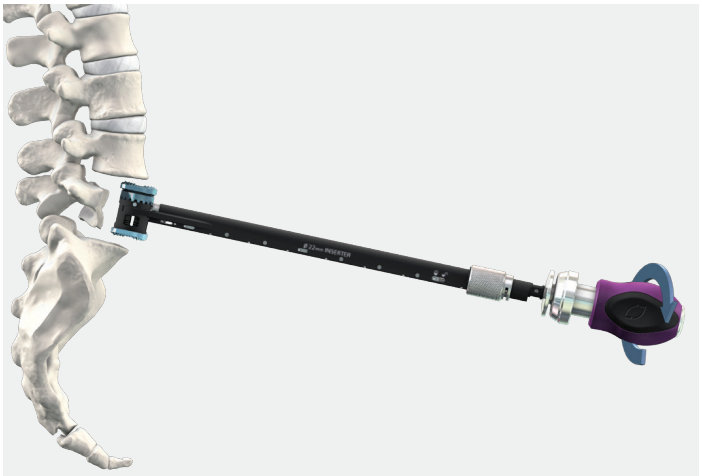


Fig. 63

Catalog

XCore 2 VBR 16 mm implant/instrument tray

Description	Catalog no.
XCore 2 titanium core, Ø 16x16–22 mm	7160022
XCore 2 titanium core, Ø 16 x18–25 mm	7160025
XCore 2 titanium core, Ø 16x23–35 mm	7160035
XCore 2 titanium core, Ø 16x26–41 mm	7160041
XCore 2 titanium core, Ø 16x30–49 mm	7160049
XCore 2 titanium core, Ø 16x37–63 mm	7160063
XCore 2 titanium core, Ø 16x43–75 mm	7160075
XCore 2 titanium endcap, 16 mm round 0° Ø 16	5161600
XCore 2 titanium endcap, 16 mm round 4° Ø 16	5161604
XCore 2 titanium endcap, 18 mm round 0° Ø 16	5181800
XCore 2 titanium endcap, 18 mm round 4° Ø 16	5181804
XCore 2 titanium endcap, Ø 16x16x30 mm 0°	5163000
XCore 2 titanium endcap, Ø 16x1x40 mm 0°	5164000
XCore 2 titanium endcap, Ø 16x16x30 mm -4°	5163014
XCore 2 titanium endcap, Ø 16x16x40 mm -4°	5164014
XCore 2 titanium endcap, Ø 16x16x30 mm 4°	5164004
XCore 2 titanium endcap lock screw, Ø16 mm core	7110001
XCore 2 titanium lock screw, endcap	7162000
XCore 2 core trial, Ø 16 mm	7161001
Trial inserter	6539060
Endcap trial, 16x30 mm	6536130
Endcap trial, 16x40 mm	6536140
Endcap trial, 16 mm round	6538316
Endcap trial	6538318
XCore 2 height caliper	6650003
XCore 2distractor (Ø 16 mm)	6651004
XCore 2 long distractor (Ø 16 mm)	6652004
XCore 2 implant loading block, Ø 16 mm	7161004
XCore 2 template, Ø 16 mm and Ø 18 mm	9401427
XCore 2 endcap lock screw driver	7110012

Description	Catalog no.
XCore 2 core tamp, Ø 16 mm	6539216
XCore 2 cylinder tamp, Ø 16 mm	6549016
Graft spatula	6539011
Endcap tamp	6539013
XCore 2 Ø 16 mm inserter	7165100
XCore 2 Ø 16 mm gearless manual expander	7165200
Inserter counter-torque handle	6790153
XCore 2 inserter slap hammer attachment, Ø 16 mm	7162016
XCore 2 core set screw driver	7110002
3-level tray base	1599102
XCore 2 univ endcap lock screw caddy base	7183005
XCore 2 univ endap lock screw caddy lid	7183105
XCore Ø 16 mm top tray	7163001
XCore Ø 16 mm middle tray	7163002
XCore Ø 16 mm bottom tray	7163003
XCore Ø 16 mm core screw caddy base	7163006
XCore Ø 16 mm core screw caddy lid	7163106
XCore IFU	9400903

XCore 2 VBR 18 mm implant/instrument tray

Description	Catalog no.
XCore 2 titanium core, Ø 18x20–25 mm	7180025 A
XCore 2 titanium core, Ø 18 x21–27 mm	7180027 A
XCore 2 titanium core, Ø 18x24–33 mm	7180033 A
XCore 2 titanium core, Ø 18x28–41 mm	7180041 A
XCore 2 titanium core, Ø 18x35–55 mm	7180055 A
XCore 2 titanium core, Ø 18x41–67 mm	7180067 A
XCore 2 titanium core, Ø 18x47–79 mm	7180079 A
XCore 2 titanium core, Ø 18x68–121 mm	7180121 A
XCore 2 titanium endcap, 18 mm round 0° Ø 18	6181800
XCore 2 titanium endcap, 18 mm round 4° Ø 18	6181804
XCore 2 titanium endcap, 22 mm round 0° Ø 18	6222200
XCore 2 titanium endcap, 22 mm round 4° Ø 18	6222204
XCore 2 titanium endcap, 22 mm round 8° Ø 18	6222208
XCore 2 titanium endcap, 26 mm round 0° Ø 18	6262600
XCore 2 titanium endcap, 26 mm round 4° Ø 18	6262604
XCore 2 titanium endcap, 26 mm round 8° Ø 18	6262608
XCore 2 titanium endcap, Ø 18x18x30 mm -4°	6183014
XCore 2 titanium endcap, Ø 18x18x30 mm 0°	6183000
XCore 2 titanium endcap, Ø 18x18x30 mm 4°	6183004
XCore 2 titanium endcap, Ø 18x18x30 mm 8°	6183008
XCore 2 titanium endcap, Ø 18x18x40 mm -4°	6184014
XCore 2 titanium endcap, Ø 18x18x40 mm 0°	6184000
XCore 2 titanium endcap, Ø 18x18x40 mm 4°	6184004
XCore 2 titanium endcap, Ø 18x18x40 mm 8°	6184008
XCore 2 titanium endcap, Ø 18x18x50 mm -4°	6185014
XCore 2 titanium endcap, Ø 18x18x50 mm 0°	6185000
XCore 2 titanium endcap, Ø 18x18x50 mm 4°	6185004
XCore 2 titanium endcap, Ø 18x18x50 mm 8°	6185008
XCore 2 titanium endcap, Ø 18x22x30 mm 0°	6223000
XCore 2 titanium endcap, Ø 18x22x30 mm 4°	6223004
XCore 2 titanium endcap, Ø 18x22x30 mm 8°	6223008
XCore 2 titanium endcap, Ø 18x22x30 mm 12°	6223012

Description	Catalog no.
XCore 2 titanium endcap, Ø 18x22x40 mm 8°	6224008
XCore 2 titanium endcap, Ø 18x22x40 mm 12°	6224012
XCore 2 titanium endcap, Ø 18x22x50 mm 0°	6225000
XCore 2 titanium endcap, Ø 18x22x50 mm 4°	6225004
XCore 2 titanium endcap, Ø 18x22x50 mm 8°	6225008
XCore 2 titanium endcap, Ø 18x22x50 mm 12°	6225012
XCore 2 titanium endcap, Ø 18x22x60 mm 0°	6226000
XCore 2 titanium endcap, Ø 18x22x60 mm 4°	6226004
XCore 2 titanium endcap, Ø 18x22x60 mm 8°	6226008
XCore 2 titanium endcap, Ø 18x22x60 mm 12°	6226012
XCore 2 titanium lock screw, endcap	7162000
XCore 2 titanium core lock screw, Ø 18 and Ø 22	7110003
Trial inserter	6539060
XCore 2 endcap trail, Ø 18 mm	7181001
Endcap trial, 18x30 mm	6538130
Endcap trial, 18x40 mm	6538140
Endcap trial, 18x50 mm	6538150
Endcap trial, 22x30 mm	6538230
Endcap trial, 22x40 mm	6538240
Endcap trial, 22x50 mm	6538250
Endcap trial, 22x60 mm	6538260
Endcap trial, 18 mm round	6538318
Endcap trial, 22 mm round	6538322
Endcap trial, 26 mm round	6538326
XCore 2 height caliper	6650003
XCore 2 distractor (Ø 18 and Ø 22 mm)	6650004
XCore 2 implant loading block, Ø 18 mm	7181004
XCore 2 template, Ø 16 and Ø 18 mm	9401427
XCore 2 endcap lock screw driver	7110012
Endcap tamp	6539013
XCore 2 core tamp, Ø 18 mm	6539218
XCore 2 cylinder tamp, Ø 18 mm	6549218

XCore 2 VBR 18 mm implant/instrument tray (cont.)

Description	Catalog no.
Graft spatula	6539011
XCore 2 Ø 18 inserter	7185100
XCore 2 inserter handle	7110004
XCore 2 Ø 18 gearless manual expander	7185200
Inserter counter-torque handle	6790153
XCore 2 core set screw driver	7110002
Tray lid	8801333
3-level tray base	1599102
XCore 2 Ø 18 top tray	7183001
XCore 2 Ø 18 middle tray	7183002
XCore 2 Ø 18 bottom tray	7183003
XCore 2 Ø 18 and Ø 22 core screw caddy base	7183006
XCore 2 Ø 18 and Ø 22 core screw caddy lid	7183106
XCore 2 univ endcap lock screw caddy base	7183005
XCore 2	7183105
XCore IFU	9400903

XCore 2 VBR 22 mm implant/instrument tray

Description	Catalog no.
X-Core 2 titanium core, Ø 22x20–25 mm	7220025 A
X-Core 2 titanium core, Ø 22x21–27 mm	7220027 A
X-Core 2 titanium core, Ø 22x24–33 mm	7220033 A
X-Core 2 titanium core, Ø 22x28–41 mm	7220041 A
X-Core 2 titanium core, Ø 22x35–55 mm	7220055 A
X-Core 2 titanium core, Ø 22x41–67 mm	7220067 A
X-Core 2 titanium core, Ø 22x47–79 mm	7220079 A
X-Core 2 titanium core, Ø 22x68–121 mm	7220121 A
X-Core 2 titanium endcap, 22 mm round 0° Ø 22	7222200
X-Core 2 titanium endcap, 22 mm round 4° Ø 22	7222204
X-Core 2 titanium endcap, 22 mm round 8° Ø 22	7222208
X-Core 2 titanium endcap, 22 mm round 12° Ø 22	7222212
X-Core 2 titanium endcap, 26 mm round 0° Ø22	7262600
X-Core 2 titanium endcap, 26 mm round 4° Ø 22	7262604
X-Core 2 titanium endcap, 26 mm round 8° Ø 22	7262608
X-Core 2 titanium endcap, 26 mm round 12° Ø 22	7262612
X-Core 2 titanium endcap, 30 mm round 0° Ø 22	7303000
X-Core 2 titanium endcap, 30 mm round 4° Ø 22	7303004
X-Core 2 titanium endcap, 30 mm round 8° Ø 22	7303008
X-Core 2 titanium endcap, 30 mm round 12° Ø 22	7303012
X-Core 2 titanium endcap, Ø 22x22x40 mm 0°	7224000
X-Core 2 titanium endcap, Ø 22x22x40 mm 4°	7224004
X-Core 2 titanium endcap, Ø 22x22x40 mm 8°	7224008
X-Core 2 titanium endcap, Ø 22x22x40 mm 12°	7224012
X-Core 2 titanium endcap, Ø 22x22x50 mm 0°	7225000
X-Core 2 titanium endcap, Ø 22x22x50 mm 4°	7225004
X-Core 2 titanium endcap, Ø 22x22x50 mm 8°	7225008
X-Core 2 titanium endcap, Ø 22x22x50 mm 12°	7225012
X-Core 2 titanium endcap, Ø 22x22x60 mm 0°	7226000
X-Core 2 titanium endcap, Ø 22x22x60 mm 4°	7226004
X-Core 2 titanium endcap, Ø 22x22x60 mm 8°	7226008
X-Core 2 titanium endcap, Ø 22x22x60 mm 12°	7226012

XCore 2 VBR 22 mm implant/instrument tray (cont.)

Description	Catalog no.
XCore 2 titanium core lock screw, Ø 18 and Ø 22	7110003
XCore 2 titanium lock screw, endcap	7162000
Trial inserter	6539060
Endcap trial, 22x40 mm	6538240
Endcap trial, 22x50 mm	6538250
Endcap trial, 22x60 mm	6538260
Endcap trial, 22 mm round	6538322
Endcap trial, 26 mm round	6538326
Endcap trial, 30 mm round	6538330
XCore 2 height caliper	6650003
XCore 2 distractor (Ø 18 and Ø 22 mm)	6650004
XCore 2 implant loading block, Ø 22 mm	7221004
XCore 2 template, Ø 22 mm	9401428
XCore 2 endcap lock screw driver	7110012
Endcap tamp	6539013
XCore 2 core tamp, Ø 22 mm	6539222
XCore 2 cylinder tamp, Ø 22 mm	6549222
Graft spatula	6539011
XCore 2 Ø 22 mm inserter	7225100
XCore 2 inserter handle	7110004
XCore 2 Ø 22 mm gearless manual expander	7225200
Inserter counter-torque handle	6790153
XCore 2 core set screw driver	7110002
Tray lid	8801333
3-level tray base	1599102
XCore 2 Ø 22 mm top tray	7223001
XCore 2 Ø 22 mm middle tray	7223002
XCore 2 Ø 22 mm bottom tray	7223003
XCore 2 univ endcap lock screw caddy base	7183005
XCore 2 univ endcap lock screw caddy lid	7183105
XCore 2 Ø 18 and Ø 22 mm core screw caddy base	7183006
XCore 2 Ø 18 and Ø 22 mm core screw caddy lid	7183106
XCore IFU	9400903

Instructions for use—US

Description

The NuVasive X-Core Expandable VBR System is manufactured from Ti-6Al-4V ELI conforming to ASTM F136 and ISO 5832-3. The implants are available in a variety of sizes to accommodate anatomical conditions.

Indications for use

The NuVasive X-Core Expandable VBR System is a vertebral body replacement device indicated for use in the thoracolumbar spine (T1 to L5) to replace a diseased or damaged vertebral body caused by tumor or fracture, to restore height of a collapsed vertebral body, and to achieve decompression of the spinal cord and neural tissues. The NuVasive X-Core Expandable VBR System is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the thoracic and lumbar spine. Allograft or autograft material may be used at the surgeon's discretion.

Contraindications

Contraindications include, but are not limited to:

1. Infection, local to the operative site.
2. Signs of local inflammation.
3. Patients with known sensitivity to the materials implanted.
4. Patients who are unwilling to restrict activities or follow medical advice.
5. Patients with inadequate bone stock or quality.
6. Patients with physical or medical conditions that would prohibit beneficial surgical outcome.
7. Use with components of other systems.
8. Reuse or multiple uses.

Potential adverse events and complications

AAs with any major surgical procedures, there are risks involved in orthopedic surgery. Infrequent operative and postoperative complications that may result in the need for additional surgeries include: early or late infection; damage to blood vessels, spinal cord or peripheral nerves; dysphagia; dysphonia; dural tear or CSF leak; esophageal injury; worsened neurologic status; vertebral artery injury; pulmonary emboli; loss of sensory and/or motor function; impotence; and permanent pain and/or deformity. Rarely, some complications may be fatal.

Potential risks identified with the use of this system, which may require additional surgery, include:

- Bending, fracture or loosening of implant component(s)
- Loss of fixation
- Nonunion or delayed union
- Fracture of the vertebra
- Implant subsidence
- Neurological, vascular or visceral injury
- Spinal cord or nerve root injury (particularly C5) due to over-distraction
- Nerve damage due to surgical trauma
- Metal sensitivity or allergic reaction to a foreign body
- Infection
- Decrease in bone density due to stress shielding
- Pain, discomfort or abnormal sensations due to the presence of the device
- Bursitis
- Dural leak
- Paralysis
- Death

Warnings, cautions and precautions

- The subject device is intended for use only as indicated.
- The implantation of spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- Correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size of the implant. While proper selection can minimize risks, the size and shape of human bones present limitations on the size and strength of implants. Metallic internal fixation devices cannot withstand the activity levels and/or loads equal to those placed on normal, healthy bone. These devices are not designed to withstand the unsupported stress of full weight or load bearing alone.
- Based on fatigue testing results, when using the X-Core Expandable VBR System, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.
- Careful preoperative planning, intraoperative sizing, radiographic confirmation of proper spinal segment height restoration, and intraoperative neuromonitoring are critical in avoiding spinal cord and nerve root injuries that may be caused by over-distraction. Do not over-distract the spinal segment.
- Careful preoperative planning and intraoperative sizing to maximize endplate coverage are important in helping avoid implant subsidence.
- Caution must be taken due to potential patient sensitivity to materials. Do not implant in patients with known or suspected sensitivity to the aforementioned materials.
- These devices can break when subjected to the increased load associated with delayed union or nonunion. Internal fixation appliances are load-sharing devices that hold bony structures in alignment until healing occurs. If healing is delayed, or does not occur, the implant may eventually loosen, bend, or break. Loads

on the device produced by load bearing and by the patient's activity level will dictate the longevity of the implant.

- Corrosion of the implant can occur. Implanting metals and alloys in the human body subjects them to a constantly changing environment of salts, acids, and alkalis, which can cause corrosion. Placing dissimilar metals (e.g., titanium and stainless steel) in contact with each other can accelerate the corrosion process, which in turn, can enhance fatigue fractures of implants. Consequently, every effort should be made to use compatible metals and alloys in conjunction with each other.
- When used at more than two levels, supplemental fixation should include posterior fixation which is cleared by the FDA.
- Avoid excessive distraction to decrease the risk of overdistraction causing neurologic injury.
- Place supplemental fixation (e.g., anterior plate and/or posterior cervical screw fixation system) at the necessary levels to reduce the risk of implant subsidence and vertebral body fracture as well as the potential for implant migration. Additional posterior supplemental fixation may be required in some cases for adequate stabilization. See the supplemental fixation system instructions for use and Surgical Technique for instructions.
- When assembling the construct with static cores, only utilize dismantlable inserters.
- When utilizing Ø16mm static cores, refer to the Surgical Technique for instructions on removing the internal gear drive from the appropriate dismantlable inserter.
- All components should be final tightened per the specifications in the Surgical Technique. Implants should not be tightened past the locking point, as damage to the implant may occur.
- To help ensure proper inserter/implant engagement, the inserter's colored distal tip must face up toward the like-colored spinning sleeve of the implant.
- To help ensure proper anatomical alignment, the rounded corners of the X-Core shape endcaps must face anterior during implant construction and placement.
- Care should be taken to confirm that all components are ideally fixated prior to closure.
- Refer to Cleaning and Sterilization Instructions below for all non-sterile parts.
- Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.

Patient Education

Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.

Single Use/Do Not Re-Use:

Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, material degradation, potential leachables, and transmission of infectious agents.

MRI Safety Information:

Please refer to Refer to the NuVasive X-Core Expandable VBR System eIFU for MR safety information.

Compatibility:
Do not use X-Core Expandable VBR System with components of other systems. Unless stated otherwise, NuVasive devices are not to be combined with the components of another system.

PRE-OPERATIVE WARNINGS

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient condition and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the X-Core implants. The implants should not be scratched or damaged. Implants and instruments should be protected during storage and from corrosive environments.

   For Sterile Implants: Assure highly aseptic surgical conditions, and use aseptic technique when removing the X-Core implant from its packaging. Inspect the implant and packaging for signs of damage, including scratched or damaged devices or damage to the sterile barrier. Do not use the X-Core implants if there is any evidence of damage.
4. Refer to Cleaning and Sterilization Instructions below for all non-sterile parts.
5. Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.

POST-OPERATIVE WARNINGS

During the postoperative phase it is of particular importance that the physician keeps the patient well informed of all procedures and treatments.

Damage to the weight-bearing structures can give rise to loosening of the components, dislocation and migration as well as to other complications. To help ensure the earliest possible detection of such catalysts of device dysfunction, the devices must be checked periodically postoperatively, using appropriate radiographic techniques.

It is important to instruct the patient in appropriate postoperative activity restrictions to minimize the risk of potential vertebral body fracture and implant migration.

Instructions for use—OUS

Description

The NuVasive X-CORE Expandable VBR System is manufactured from Ti-6Al-4V ELI conforming to ASTM F136 and ISO 5832-3. The implants are available in a variety of sizes to accommodate anatomical conditions.

Indications for use

The NuVasive X-CORE Expandable VBR System is a vertebral body replacement device indicated for use in the thoracolumbar spine (T1 to L5) to replace a diseased or damaged vertebral body caused by tumor or fracture, to restore height of a collapsed vertebral body, and to achieve decompression of the spinal cord and neural tissues. The NuVasive X-CORE Expandable VBR System is intended to be used with supplemental internal spinal fixation systems.

Contraindications

Contraindications include, but are not limited to:

1. Infection, local to the operative site.
2. Signs of local inflammation.
3. Patients with known sensitivity to the materials implanted.
4. Patients who are unwilling to restrict activities or follow medical advice.
5. Patients with inadequate bone stock or quality.
6. Patients with physical or medical conditions that would prohibit beneficial surgical outcome.
7. Use with components of other systems.
8. Reuse or multiple uses.

Potential adverse events and complications

As with any major surgical procedures, there are risks involved in orthopedic surgery. Infrequent operative and postoperative complications that may result in the need for additional surgeries include: early or late infection; damage to blood vessels, spinal cord or peripheral nerves; dysphagia; dysphonia; dural tear or CSF leak; esophageal injury; worsened neurologic status; vertebral artery injury; pulmonary emboli; loss of sensory and/or motor function; impotence; and permanent pain and/or deformity. Rarely, some complications may be fatal.

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- Loss of fixation
- Nonunion or delayed union
- Fracture of the vertebra
- Implant subsidence
- Neurological, vascular or visceral injury
- Spinal cord or nerve root injury (particularly C5) due to over-distraction
- Nerve damage due to surgical trauma
- Metal sensitivity or allergic reaction to a foreign body
- Infection
- Decrease in bone density due to stress shielding
- Pain, discomfort or abnormal sensations due to the presence of the device
- Bursitis
- Dural leak
- Paralysis
- Death

WARNINGS, CAUTIONS AND PRECAUTIONS

- The subject device is intended for use only as indicated.
- The implantation of spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
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- Based on fatigue testing results, when using the X-Core Expandable VBR System, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.
- Careful preoperative planning, intraoperative sizing, radiographic confirmation of proper spinal segment height restoration, and intraoperative neuromonitoring are critical in avoiding spinal cord and nerve root injuries that may be caused by over-distraction. Do not over-distract the spinal segment.
- Careful preoperative planning and intraoperative sizing to maximize endplate coverage are important in helping avoid implant subsidence.
- Caution must be taken due to potential patient sensitivity to materials. Do not implant in patients with known or suspected sensitivity to the aforementioned materials.
- These devices can break when subjected to the increased load associated with delayed union or nonunion. Internal fixation appliances are load-sharing devices that hold bony structures in alignment until healing occurs. If healing is delayed, or does not occur, the implant may eventually loosen, bend, or break. Loads on the device produced by load bearing and by the patient's activity level will dictate the longevity of the implant.

- Corrosion of the implant can occur. Implanting metals and alloys in the human body subjects them to a constantly changing environment of salts, acids, and alkalis, which can cause corrosion. Placing dissimilar metals (e.g., titanium and stainless steel) in contact with each other can accelerate the corrosion process, which in turn, can enhance fatigue fractures of implants. Consequently, every effort should be made to use compatible metals and alloys in conjunction with each other.
- When used at more than two levels, supplemental fixation should include posterior fixation.
- Avoid excessive distraction to decrease the risk of overdistraction causing neurologic injury.
- Place supplemental fixation (e.g., anterior plate and/or posterior cervical screw fixation system) at the necessary levels to reduce the risk of implant subsidence and vertebral body fracture as well as the potential for implant migration. Additional posterior supplemental fixation may be required in some cases for adequate stabilization. See the supplemental fixation system Instructions for Use and Surgical Technique for instructions.
- When assembling the construct with static cores, only utilize dismantlable inserters.
- When utilizing Ø16mm static cores, refer to the Surgical Technique for instructions on removing the internal gear drive from the appropriate dismantlable inserter.
- All components should be final tightened per the specifications in the Surgical Technique. Implants should not be tightened past the locking point, as damage to the implant may occur.
- To help ensure proper inserter/implant engagement, the inserter's colored distal tip must face up toward the like-colored spinning sleeve of the implant.
- To help ensure proper anatomical alignment, the rounded corners of the X-Core shape endcaps must face anterior during implant construction and placement.
- Care should be taken to confirm that all components are ideally fixated prior to closure.

Patient Education:
Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.

Single Use/Do Not Re-Use:
Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, material degradation, potential leachables, and transmission of infectious agents.

Magnetic resonance (MR) safety:
Refer to the X-Core System eIFU for MR safety information.

Compatibility: Do not use X-Core with components of other systems. Unless stated otherwise, NuVasive devices are not to be combined with the components of another system.

Preoperative warnings

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient condition and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the X-Core implants. The implants should not be scratched or damaged. Implants and instruments should be protected during storage and from corrosive environments.
4. Refer to Cleaning and Sterilization Instructions below for all non-sterile parts.
5. Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.

Post-operative warnings

During the postoperative phase it is of particular importance that the physician keeps the patient well informed of all procedures and treatments.

Damage to the weight-bearing structures can give rise to loosening of the components, dislocation and migration as well as to other complications. To help ensure the earliest possible detection of such catalysts of device dysfunction, the devices must be checked periodically postoperatively, using appropriate radiographic techniques.

It is important to instruct the patient in appropriate postoperative activity restrictions to minimize the risk of potential vertebral body fracture and implant migration.

Please refer to the X-Core System IFU found at **www.nuvasive.com/eifu** for additional important labeling information

Notes

Notes

References

1. Smith WD, Dakwar E, Le TV, et al. Minimally invasive surgery for traumatic spinal pathologies: a mini-open, lateral approach in the thoracic and lumbar spine. *Spine* 2010; 35(26 Suppl): S338-S346.
2. Pekmezci M, McDonald E, Kennedy A, et al. Can a Novel Rectangular Footplate Provide Higher Resistance to Subsidence When Compared to Circular Footplates?: An Ex Vivo Biomechanical Study. *Spine* 2012; In Press.

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