NFlex. Semi-rigid rods for posterior lumbar stabilization.

Technique Guide
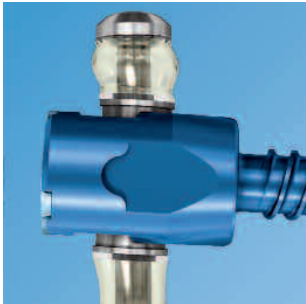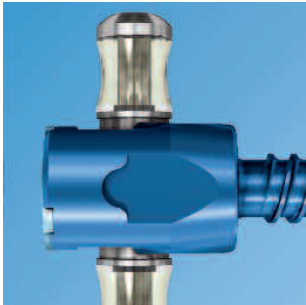

⊕ SYNTHES® Instruments and implants
approved by the AO Foundation

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Image intensifier control

Warning
This description alone does not provide sufficient background for direct use of the instrument set. Instruction by a surgeon experienced in handling these instruments is highly recommended.

Reprocessing, Care and Maintenance of Synthes Instruments
For general guidelines, function control and dismantling of multi-part instruments, please refer to: www.synthes.com/reprocessing

NFlex. Semi-rigid rods for posterior lumbar stabilization.

Pre-curved and straight rods for mono- and multi-segmental posterior stabilization with Click'X or Pangea
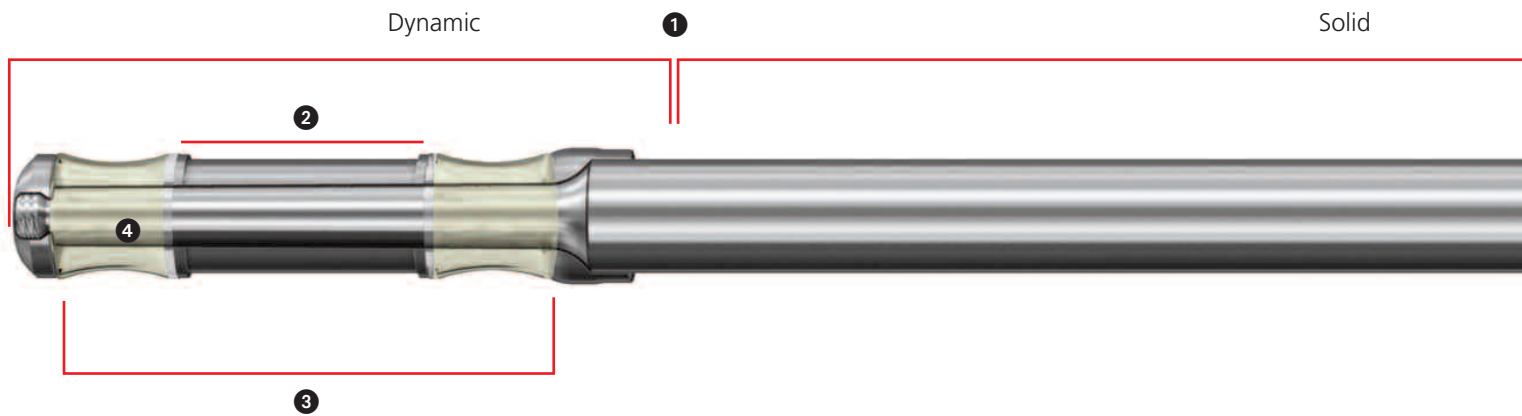
Dynamic   ❶   Solid

❶ **Dynamic and solid ends**
– A rod with transitional rigidity
– One solution for posterolateral fusion with dynamic stabilization

❷ **Titanium ring**
– Allows for sliding and toggling coupled motion
– Sliding motion as ring slides up and down the core
– Toggling motion as ring toggles against the core

❸ **Polymer sleeve**
– Polymer bumper that allows for controlled titanium ring motion in flexion, extension, lateral bending and axial rotation at the dynamic level

❹ **Titanium alloy core**
– Tapered core design providing transitional rigidity

Decreasing rigidity

Uninstrumented level

Dynamic level

Rigid level
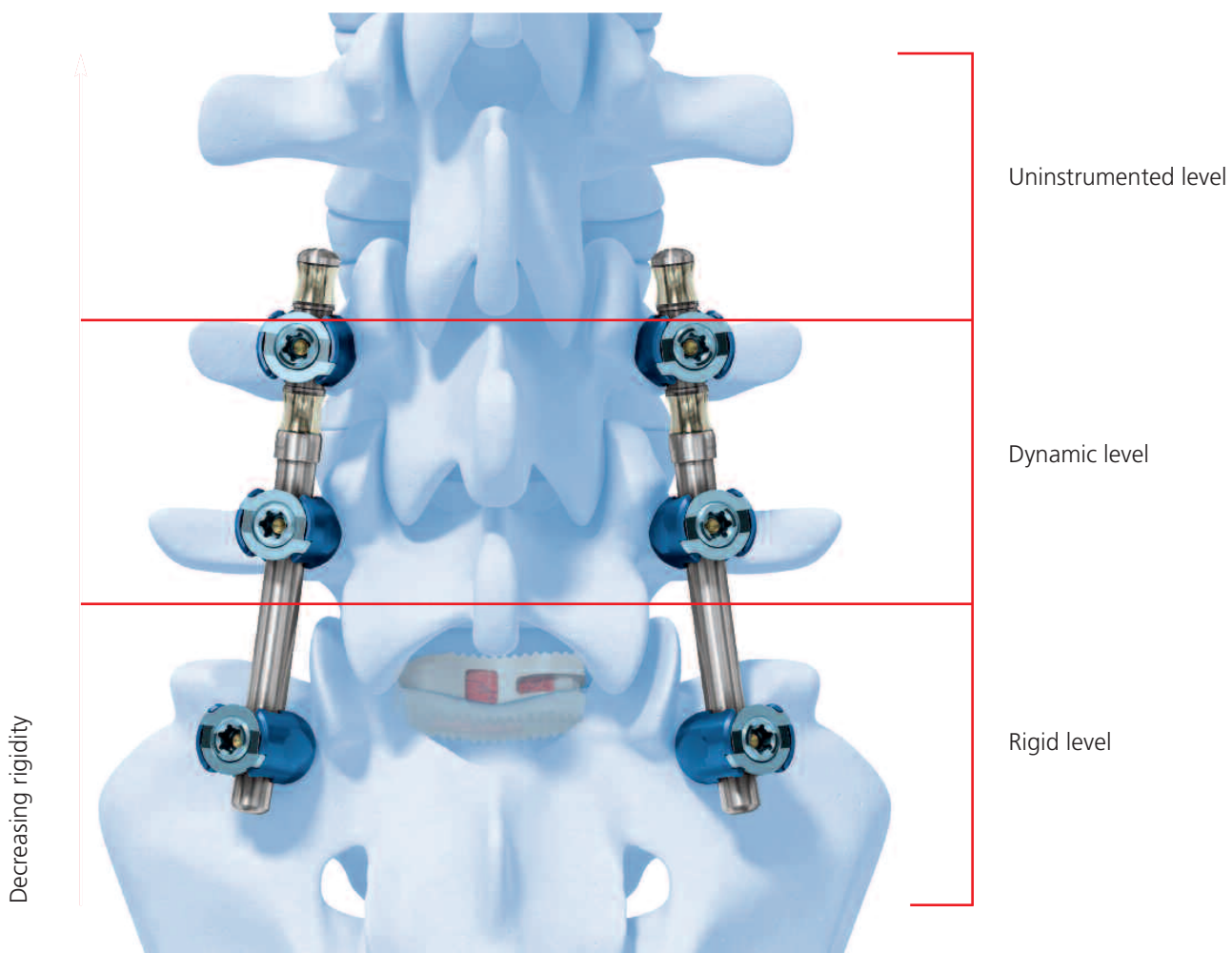
Indications and Contraindications

The NFlex Stabilization System is a rod designed to be used with either the Pangea or Click'X pedicle screw systems (please reference each specific Surgical Technique Guide for additional information). These pedicle screw systems are comprised of a variety of pedicle screw sizes and locking caps that can be uniquely fitted with specific instruments for each individual case.

Intended purpose

The NFlex Stabilization System is intended for use with pedicle screw* fixation in skeletally mature patients to provide controlled dynamic stabilization of the lumbosacral spine.

Indications

The NFlex Stabilization System can be used for the following indications:
– Spinal Stenosis with or without radiculopathy
– Degenerative Disc Disease (DDD) with or without retrolisthesis
– Soft disc protrusions
– Facet syndrome due to facet osteoarthritis

Contraindications

Do not implant in cases of:
– Severe osteoporosis*
– Spinal fracture or dislocation
– Spinal deformities
– Spinal tumor
– Infection
– Morbid Obesity (BMI > 40)

Contraindications specific to the dynamic level

– Segmental instability
– Destabilizing decompression (e.g. greater than 50% facetectomy, laminectomy inducing sagittal or rotational instability)
– Isthmic and degenerative spondylolisthesis
– Previous lumbar level fusion attempt

*Governed by the indications of the pertaining pedicle screw system.

Patient exclusion recommendations

In selecting patients for NFlex, the following exclusion criteria are important for the outcome and success of the procedure:
– Patients requiring multi-level correction in the sagittal or coronal plane
– Patients requiring corrections at the semi-rigid level
– Segments with gross translational or flexion/extension instabilities at the semi-rigid level
– <11 mm between polyaxial screwheads at the semi-rigid level
– Patient's activity level, weight and musculoskeletal condition must be considered

NFlex Principles

Principles of dynamic stabilization

The NFlex Stabilization System enables dynamic stabilization of the posterior lumbar spine (1). To achieve successful outcomes with the NFlex Stabilization System, it is important to understand and consider the differences between rigid and dynamic stabilization. The principles of dynamic stabilization include:
– Decreased stiffness compared to traditional rigid stabilization
– Increased load sharing with surrounding anatomical structures

Dynamic constructs provide less resistance to spinal loading and motion, and warrant special patient selection and intra-operative handling consideration.

The NFlex rod motion allows more load transmission to the anterior column compared to a rigid fusion.

1
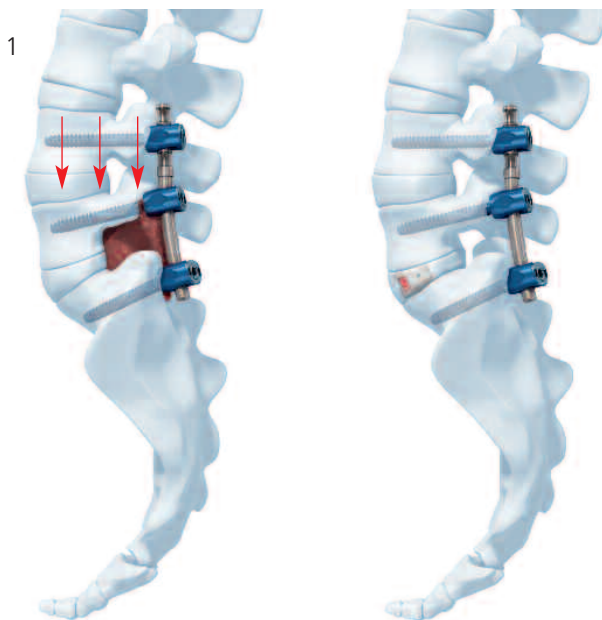
Combined posterolateral fusion
with dynamic stabilization.

Combined interbody fusion with
dynamic stabilization.

Function of the NFlex rod

The main goal of the NFlex surgical technique is to implant the rod so that the patient can utilize the full range of motion and load-sharing capabilities of the device. To accomplish this:

– Implant the dynamic end in an unstressed, unloaded state to achieve a passive rod fit.
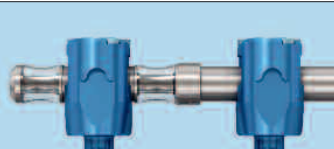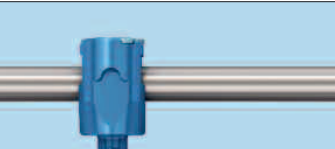– Position the rods to complement the motion of the segment.
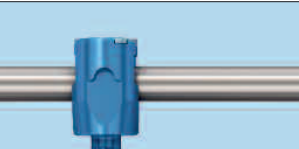
Preloading the dynamic end of the NFlex rod could compromise the dynamic performance of the titanium ring and polymer sleeve construct and overload the titanium core, causing the rod to fail. Both patient pathology and intraoperative technique can contribute to preloading the NFlex rod.

The NFlex rod is in an unloaded (passive) state when there is no ring toggling and/or sliding relative to the core (2).

Unloaded state   Loaded state
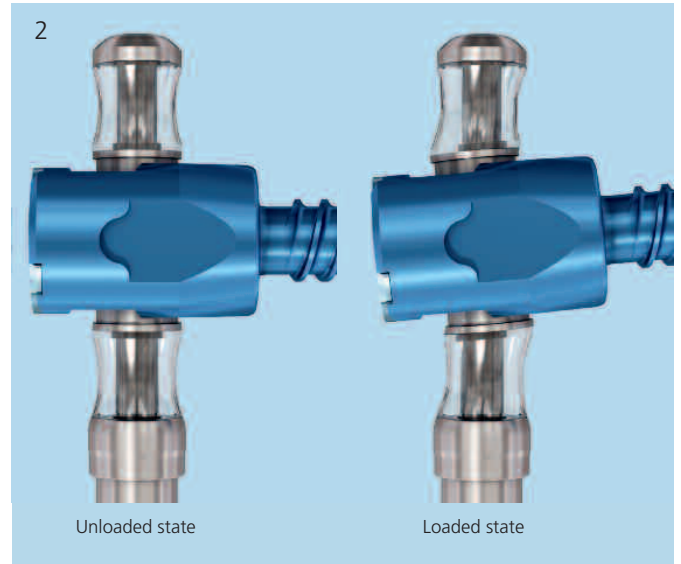
The NFlex rod should be inserted in an unloaded, passive state.

Appropriate use of the NFlex rod

	Semi-rigid Level (Dynamic)	Adjacent rigid level (Solid)	2nd rigid level (Solid)
Correction of kyphosis (flat back)	No	Yes, if correction **does not** preload dynamic unit	Yes, if correction **does not** preload dynamic unit
Correction of sagittal or coronal alignment	No	Yes, if correction **does not** preload dynamic unit	Yes, if correction **does not** preload dynamic unit
Spondylolisthesis or retrolisthesis reduction	No	Yes, if correction **does not** preload dynamic unit and with anterior support **only**	Yes
Rod persuasion	No	Minimal	Yes
Segmental compression or distraction	No	Yes, if correction **does not** preload dynamic unit	Yes
Hypermobility (assessed by surgeon)	No	Yes	Yes
Facetectomy or facet insufficiency	No	No	Yes
Laminectomy	No	No	Yes, only if adjacent segment is also fused
Laminotomy	Yes, but segment must be stable **prior** to implantation	Yes	Yes
Disc height restoration	Yes, with anterior support **only**	Yes, if correction **does not** preload dynamic unit	Yes

Contributors to excessive rod loading:

Patient pathology factors
– Sagittal or coronal spinal deformities
– Spondylolisthesis
– Facet insufficiency at the dynamic level
– Hypermobility at the dynamic level

Intraoperative factors
– Improper patient positioning
– Rod persuasion
– Compression or distraction at the semi-rigid level
– Instability induced by laminectomy or facetectomy

Preoperative Planning

A detailed and correct assessment of the indication is the key for successful results using the NFlex stabilization system.

If conservative treatment methods have failed to yield positive results, a diagnosis can be made on the basis of indication profile as to whether the use of NFlex could be a promising option for the patient in question.

Basic diagnosis
– X-ray, anterior/posterior (AP) and lateral
– X-ray, flexion/extension and lateral inclination
  (patient standing)

NFlex rods should be placed bilaterally only.

The segment intended for semi-rigid stablization must provide enough stability to load share with the NFlex rod postoperatively. A solid rod should be used to stabilize any segment with questionable load sharing capabilities.

Note: Candidates for the NFlex rod should not require multi-level spinal correction in the sagittal or coronal plane or isolated correction at the semi-rigid level.

Adult patients with surgically corrected spinal deformities are predisposed to return to their preoperative spinal alignment.*
Using the NFlex rod to correct spinal deformities can cause excessive loading at the dynamic level and increase the risk of rod failure.

A-P

Lateral

Flexion

Extension
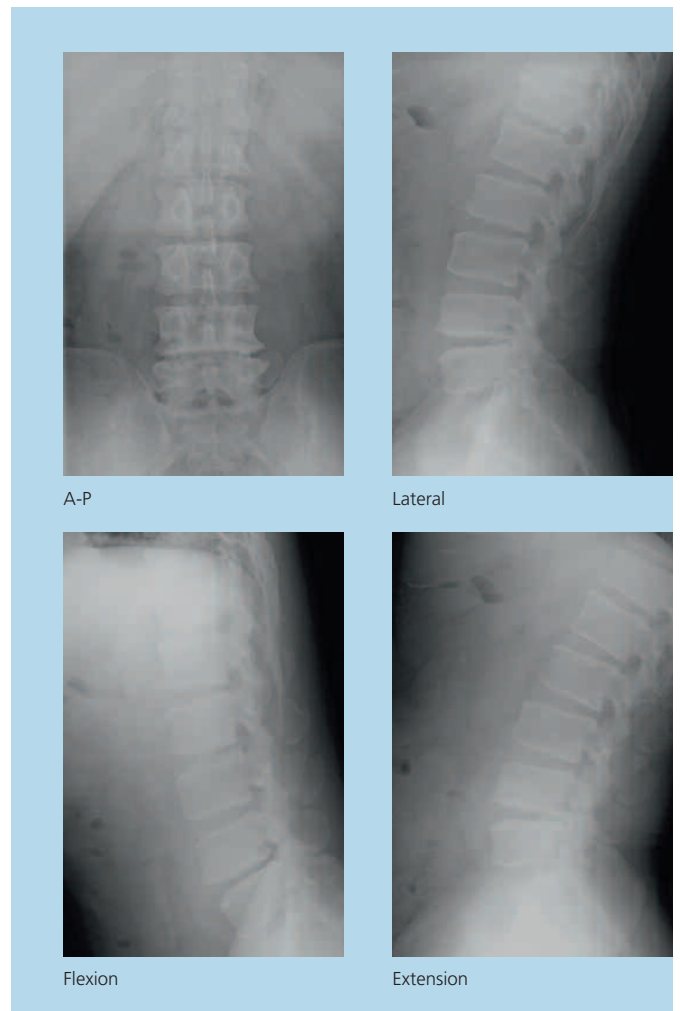
*C. Ponder, J. H. Dickson, P. R. Harrington, W. D. Erwin. (1975) Results of Harrington instrumentation and fusion in the adult idiopathic scoliosis patient. The Journal of Joint and Bone Surgery. 57: 797–801
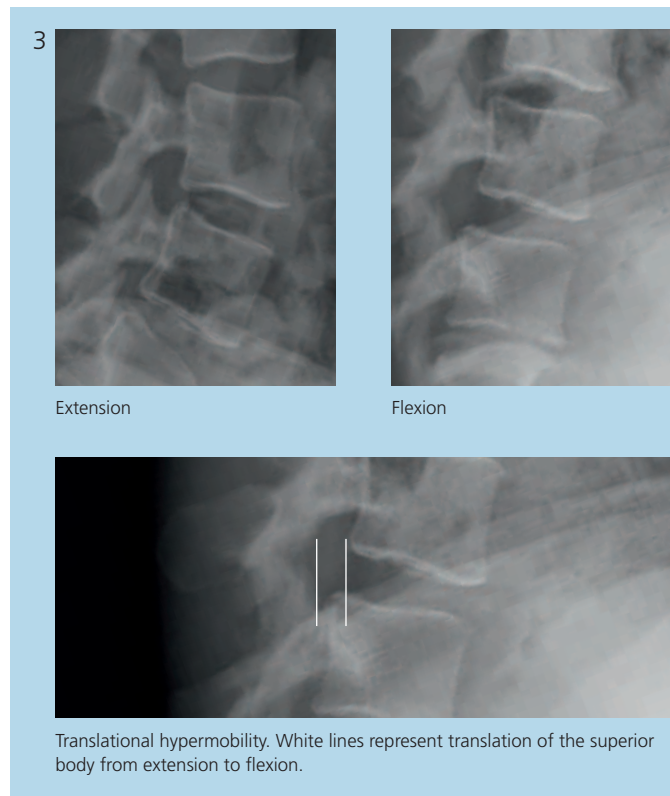
Segmental instability

The dynamic end of the NFlex rod is not designed to withstand the extreme loads that could be produced in highly unstable segments and should not be applied to segments with significant instability.

Instability may be associated with pre-existing degenerative conditions or induced intraoperatively.

Examples of instability include:
– Facetectomy or significant facet insufficiency
– Laminectomy inducing sagittal or rotational instability
– Hypermobility (3)

Important: Surgeons should carefully consider if the spinal segment intended for dynamic stabilization will provide enough stability to load share with the NFlex rod postoperatively.

Extension

Flexion

Translational hypermobility. White lines represent translation of the superior body from extension to flexion.

Patient Positioning

Position the patient prone on the operating table, with the lumbar spine in a **neutral** position.

Use a standing plain film to establish the appropriate spinal alignment.

Lateral fluoroscopy may be used to confirm that the spinal alignment matches the preoperative film.

Maintain this spinal alignment for the duration of the procedure.

Verify the correct operative level(s) and expose using a standard approach to the posterior spine.

Notes
– When implanting the NFlex rod, the patient's position on the operating table should match his/her natural preoperative standing position. This allows the rod to remain in an unloaded passive state when the patient resumes a standing position postoperatively.
– When the NFlex rod is used as a standalone device to achieve fusion, do not attempt to alter spinal alignment through patient positioning.

Insert Pedicle Screws

Care should be taken when inserting the screws to maximize the function of the dynamic end of the rod.

Guidelines for inserting screws at all levels:
– Use the longest appropriate screw lengths to allow for screw height adjustment during the rod insertion step.
– Place the screws as deep into the vertebral body as possible.
– Ensure that the polyaxial screwhead remains free to rotate in all planes.

Guidelines for inserting screws at the dynamic level (4):
– Preserve the facet joints to ensure stability of the segment.
– Place the screws lateral to the facet joints, at a latero-medial trajectory.
– Screw positioning should be similar on both sides of the segment and facilitate parallel rod placement at the dynamic level.
– A minimum of 11 mm of spacing is required between the screwheads that form the semi-rigid level.

When properly placed, screwheads should follow the natural spinal contour (a) and screws are perpendicular (b) to the contour (5).

Confirm screw placement under fluoroscopy.

Note: Use only Pangea and Click'X implants and instruments with the NFlex rods. Use of other screw systems could cause failure.
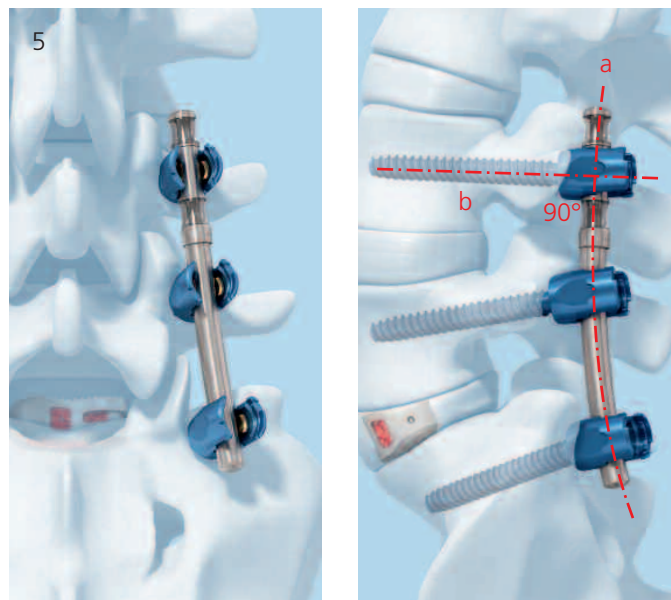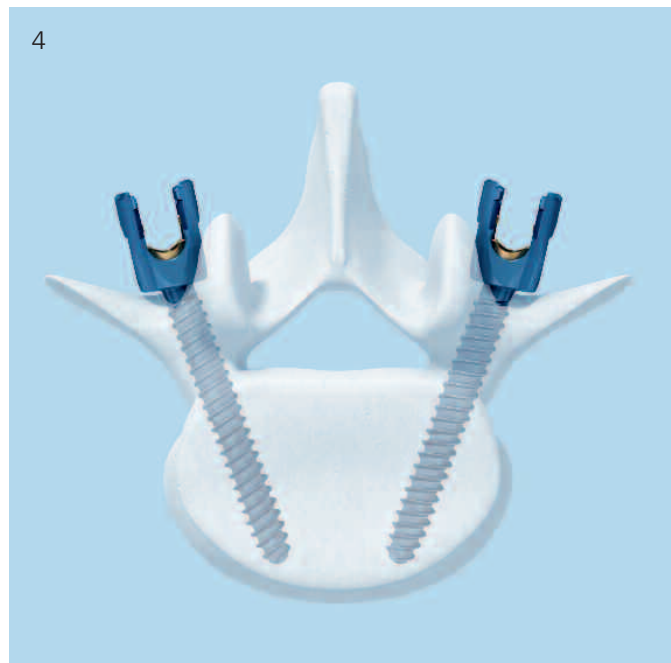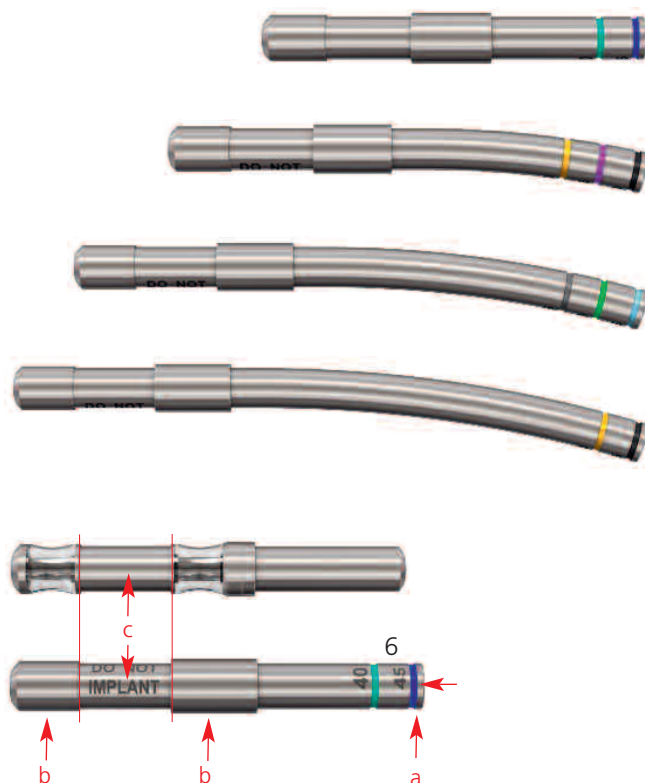
Insert Rod

1

Prepare rod

Careful rod planning and preparation is essential for proper function of the NFlex rod.

2a

Use NFlex trial implants to prepare NFlex curved rods, 40 mm–85 mm

Instruments

03.600.945– 03.600.985	NFlex Trial Implants, 45 mm–85 mm

Note: NFlex rods should be placed bilaterally only.

Note: NFlex trial implants are for sizing only. Do not implant!

The four NFlex trial implants correspond to the ten NFlex rods ranging in length from 40 mm to 85 mm. The colored bands on the trial implants (a) represent the implant sizes. Refer to the number above the colored band to determine the corresponding implant size (6).

The two thicker portions of the trial (b) represent the PCU (polycarbonate urethane) section of NFlex that cannot be placed within the screw heads. The area between corresponds to the titanium ring on the NFlex rod (c) where the screw head should be placed.

Select the appropriate NFlex trial rod that will span the screwheads. Insert the trial rod into the screwheads in the desired orientation. The trial rod should rest passively within each screwhead (7).

The screw height(s) may be adjusted to match the contour of the trial implant. Once a passive trial implant fit is achieved, determine the appropriate implant length. Select the shortest implant length that will fit entirely within the last screwhead of the construct, as indicated by the colored bands on the trial implant (d).

If a passive trial implant fit cannot be achieved after the screw height(s) have been adjusted, use the alternative technique for preparing the rod using the NFlex bending template and NFlex straight rod, 150 mm (step 2b).

Note: The NFlex straight rod, 150 mm should be used if rod bending is required to create a passive fit.

2b

Use NFlex bending template to prepare NFlex straight rod, 150 mm

Instrument

|	
03.600.426	Bending Template, for NFlex rods

Contour template

The NFlex bending template is designed to establish the contour for the NFlex straight rod, 150 mm.

The solid portion of the bending template represents the dynamic portion of the NFlex rod that cannot be contoured. The two thicker portions of the trial (a) represent the PCU section of NFlex that cannot be placed within the screw heads. The area between corresponds to the titanium ring (b) on the NFlex rod where the screw head should be placed.

Place the bending template into the screw heads, taking care that the titanium ring fits freely

Note: If adequate screwhead placement cannot be achieved at the dynamic level, the NFlex rod should not be implanted; a solid rod should be used.
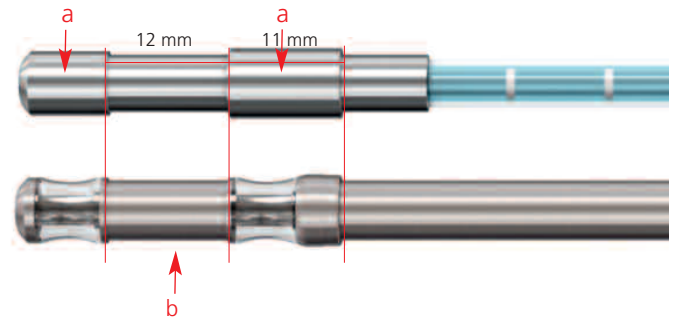
3
## Contour rod

Instrument

03.600.420   Rod Bender

Hold the NFlex rod bender with the instrument markings facing toward you. Open the handles of the rod bender as wide as possible and insert the solid end of the rod into the left side of the bender (8). The rod will not advance into the bending head past the collar. This prevents bending of the dynamic end, which could damage the rod.

Using the contoured bending template as a guide, position the portion of the rod to be contoured into the bending head (9). Slowly squeeze the handles of the rod bender together to contour the rod (10).

Open the handles to release the rod and reposition in increments down the rod to contour the rod to match the bend of the bending template. Do not reverse bend. Do not bend the rod by pulling the handles apart.

Note: Use the NFlex rod bender to contour the NFlex rod. Contour only the solid end of the NFlex rod; contouring the dynamic end of the rod will damage the rod.
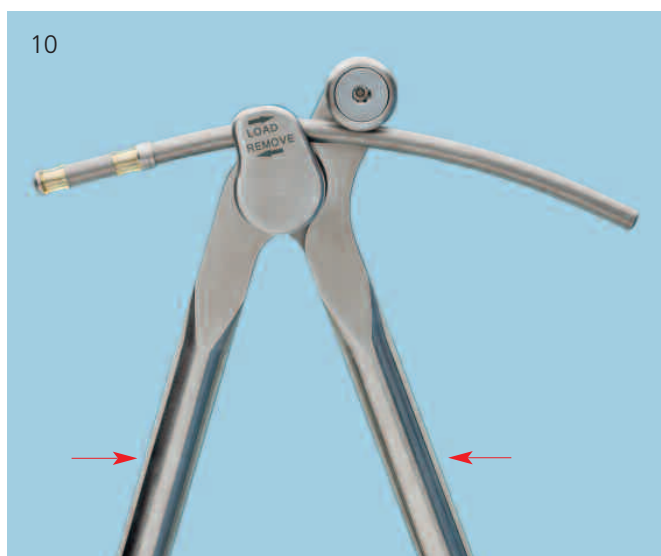
4
Insert rod

Place the NFlex rod into the pedicle screwheads, ensuring that the screwheads do not contact the polymer sleeve. Fluoroscopy may be used to confirm proper alignment of the ring within the screwhead.

The NFlex rod should rest passively in the screwheads that form the dynamic level and adjacent level to achieve a passive rod fit (11). If additional adjustment is required to achieve a passive fit, remove the rod and:
– adjust the screw height to match the contour of the rod, and/or
– carefully re-contour the rod.

If a passive rod fit cannot be achieved at the dynamic level, the NFlex rod should not be implanted.

Rod placement should complement the motion of the segment at the dynamic level. The dynamic end of the rods should be as parallel to each other as the anatomy permits.

Notes
– Do not treat/reduce spondylolisthesis at the dynamic level. The solid portion of the NFlex rod can be used to treat/reduce spondylolisthesis as long as reduction at the rigid level does not preload the rod.
– Do not use persuasion instruments such as rod pushers, rocker forks or rod persuaders to insert the NFlex rod into the screws that form the dynamic level. If necessary, gently persuade the rod into the screws outside of the dynamic level with a rod persuader.
– The ring must sit entirely within the screwhead (12).

11

Dynamic level

12

Click'X pedicle screw alignment

Pangea pedicle screw alignment
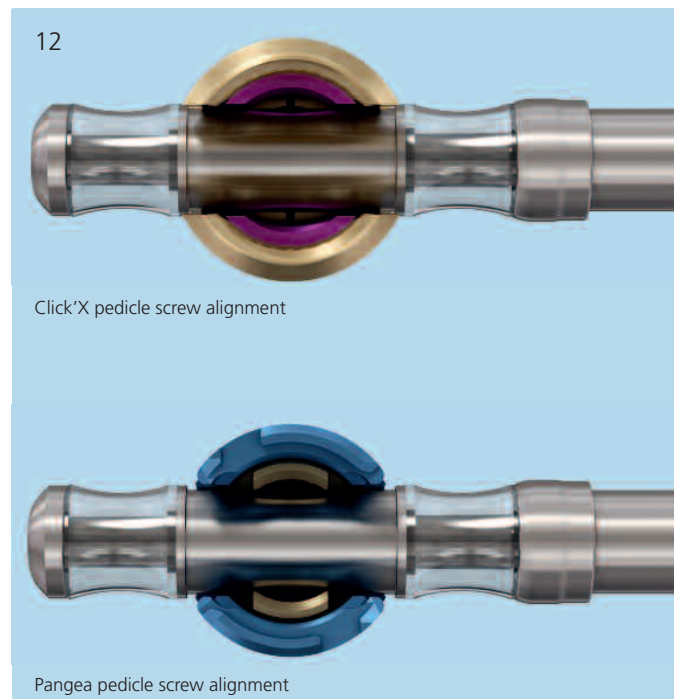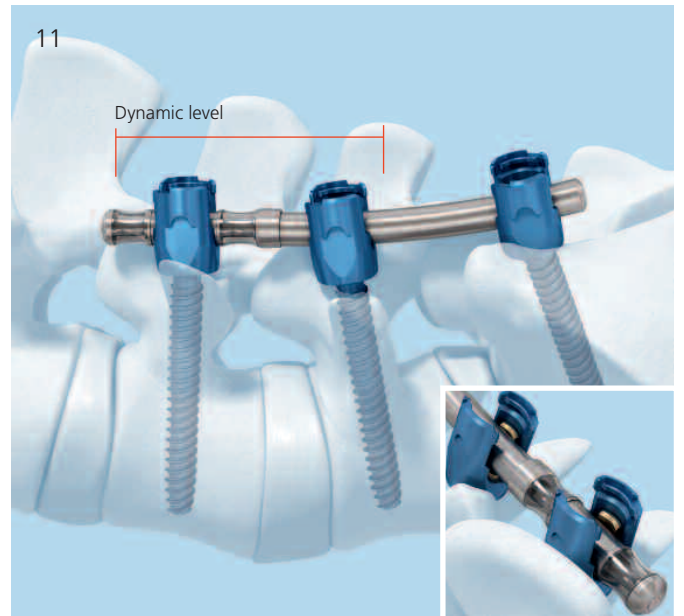
Insert Locking Caps

1
Insert caps

Pangea
Install locking caps per the recommended Pangea surgical technique.

Click'X

Instruments

|	
03.600.427	Locking Cap Insertion Tube
03.600.428	Screw Driver for Click'X Locking Cap, with knurled Handle

Using a screwdriver for the Click'X locking cap, pick up a locking cap from the implant rack. Ensure the screwdriver tongs fit firmly into the slots of the locking cap.

With the locking cap insertion tube in place, insert the locking cap and finger tighten with thumb and forefinger to capture the rod within the head.

Note: Use of locking cap insertion tube ensures correct alignment and minimizes the risk of cross threading of the locking cap.

Attach the locking cap to the screw that is adjacent to the ring ❶, followed by the caps at the fusion levels ❷. Correction manipulations at the fusion levels can now be performed. After correction has been made check that the rod sits into the saddle of the screw at the sliding ring with no preload. When this is achieved, attach the final locking cap ❸, otherwise remove all locking caps and re-contour the road at the fusion levels to achieve a better fit.

Note: Do not apply compression or distraction at the dynamic level.
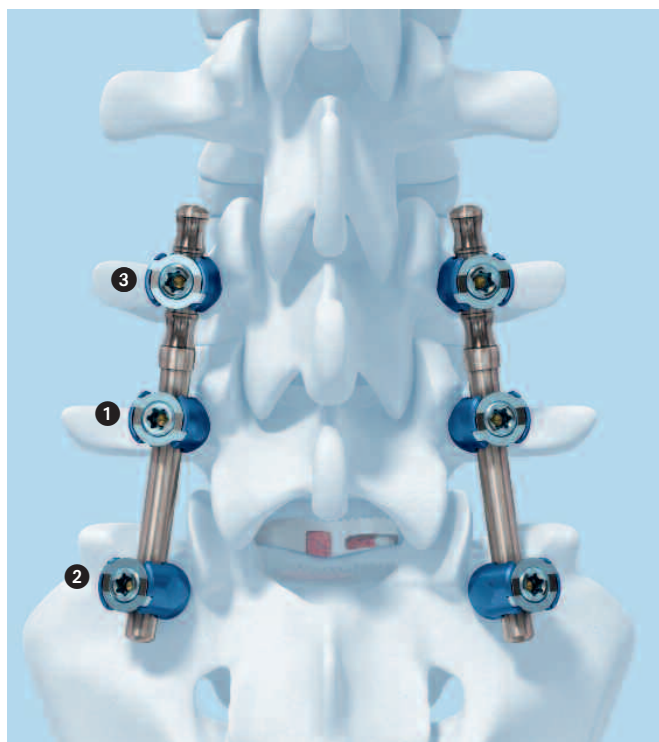
Insertion order for locking caps.

2
Final tightening caps

Perform final tightening of the caps, starting with the locking cap directly adjacent to the sliding ring ❶, then tighten the remaining caps in the fusion segments ❷. The cap at the sliding ring ❸ should always be tightened last.

Ensure that the countertorque instrument remains stationary during the final tightening procedure. Rotating the handle can damage the NFlex rod.

Note: Apply locking torque using only the torque-limiting handle and countertorque instruments specific to the Click'X or Pangea system and designed for use with NFlex rods.
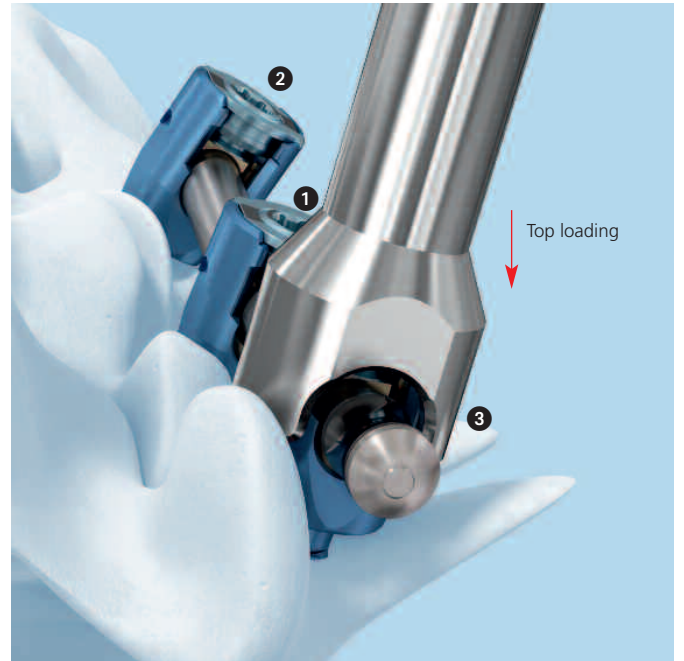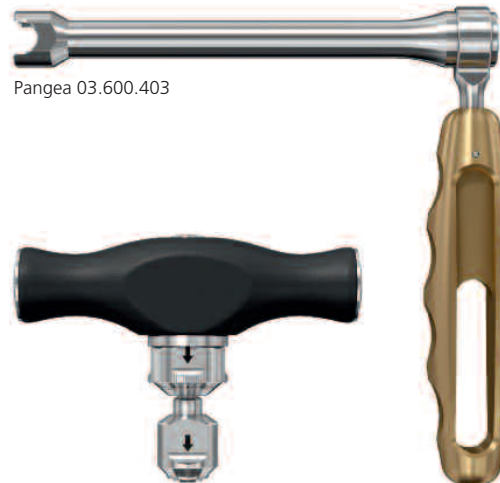
Pangea

Instruments

03.600.403	Countertorque Instrument for Pangea (NFlex)
03.620.061	T-Handle with Ratchet Wrench and with Torque Limiter, 10 Nm
03.620.022	Stardrive Screwdriver Shaft, T25 (Pangea)

Load the countertorque instrument for Pangea over the screwhead from the top, with the gold handle pointed medial or lateral.

Attach the 10 Nm T-handle with ratchet wrench to the T25 Stardrive screwdriver shaft and load it through the cannulation of the countertorque. Hold the countertorque stationary while turning the torque limiting handle to final tighten the cap.

Final tightening of Pangea construct.

Pangea 03.600.403

Pangea 03.620.061

Click'X

Instruments
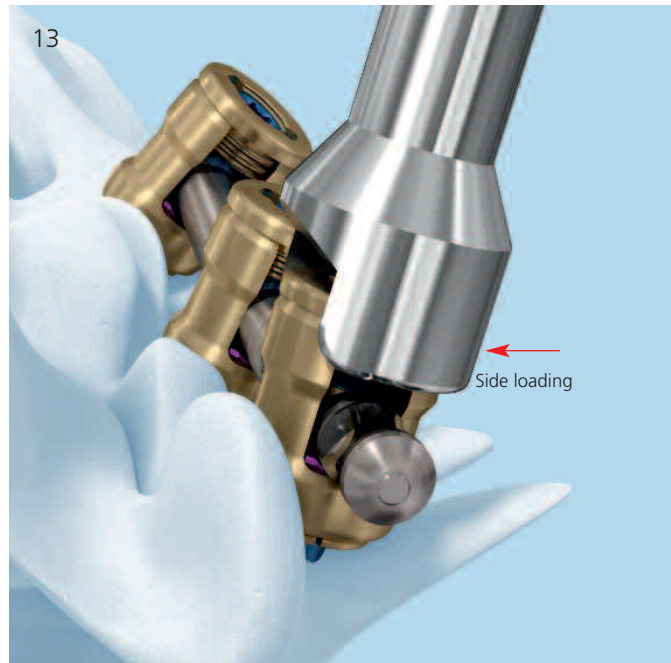
03.600.404	Countertorque, for Click'X
321.133	Torque Limiting Handle, 7 Nm
388.079	Screwdriver Shaft 3.5 mm, with Hexagonal Quick Coupling 6.0 mm, for Click'X

Optional Instrument

03.620.022	Screwdriver Shaft Stardrive, T25, short, with Hexagonal Coupling for Pangea (for Click'X Locking Cap Stardrive)

Load the Click'X countertorque around the screwhead from the medial or lateral direction (13).

Attach the 7 Nm torque limiting handle to the 3.5 mm hexagonal screwdriver shaft and load it through the cannulation of the countertorque. Hold the countertorque stationary while turning the torque limiting handle to final tighten the cap.

13

Side loading

Click'X 03.600.404

Click'X 321.133

Implants

NFlex rods, sterile

	Length (mm)		
04.600.740S	40		straight
04.600.745S	45		
04.600.750S	50		
04.600.755S	55		
04.600.760S	60		
04.600.765S	65		curved
04.600.770S	70		
04.600.775S	75		
04.600.780S	80		
04.600.785S	85		

04.600.702S	Titanium NFlex Rod, 150 mm, sterile		straight

Trial Implants

03.600.945	NFlex Trial Implant, monosegmental, straight, length 40–45 mm	
03.600.960	NFlex Trial Implant, monosegmental, curved, length 50–60 mm	
03.600.975	NFlex Trial Implant, monosegmental, curved, length 65–75 mm	
03.600.985	NFlex Trial Implant, monosegmental, curved, length 80–85 mm	

Instruments

03.600.403	Countertorque Instrument for T25, short, for Pangea	
03.600.404	Counter Torque, short, keyed for Click'X	
03.600.420	Rod Bender	
03.600.426	Bending Template for Rods ⌀ 6 mm, length 150 mm, for NFlex	
03.600.427	Locking Cap Insertion Tube, for Click'X	

NFlex Instrument Sets

Sets

01.600.201	NFlex Additional Instruments in Vario Case, for use with Click'X and Pangea
01.600.202	NFlex Additional Instruments for use with Click'X
01.600.203	NFlex Additional Instruments for use with Pangea

NFlex basic equipment for Pangea and Click'X Vario Case

68.600.015	Vario Case for NFlex Instruments, with Lid, without Contents

Instruments

03.600.945	NFlex Trial Implant, monosegmental straight, length 40–45 mm
03.600.960	NFlex Trial Implant, monosegmental curved, length 50–60 mm
03.600.975	NFlex Trial Implant, monosegmental curved, length 65–75 mm
03.600.985	NFlex Trial Implant, monosegmental curved, length 80–85 mm
03.600.426	Bending Template for Rods ⌀ 6.0 mm, length 150 mm, for Nflex
03.600.420	Rod Bender

Implants

04.600.740S	NFlex, straight, monosegmental, length 40 mm, PCU/TAV-Eli, sterile
04.600.745S	NFlex, straight, monosegmental, length 45 mm, PCU/TAV-Eli, sterile
04.600.750S	NFlex, curved, monosegmental, length 50 mm, PCU/TAV-Eli, sterile

04.600.755S	NFlex, curved, monosegmental, length 55 mm, PCU/TAV-Eli, sterile
04.600.760S	NFlex, curved, monosegmental, length 60 mm, PCU/TAV-Eli, sterile
04.600.765S	NFlex, curved, monosegmental, length 65 mm, PCU/TAV-Eli, sterile
04.600.770S	NFlex, curved, monosegmental, length 70 mm, PCU/TAV-Eli, sterile
04.600.775S	NFlex, curved, monosegmental, length 75 mm, PCU/TAV-Eli, sterile
04.600.780S	NFlex, curved, monosegmental, length 80 mm, PCU/TAV-Eli, sterile
04.600.785S	NFlex, curved, monosegmental, length 85 mm, PCU/TAV-Eli, sterile
04.600.702S	NFlex, straight, monosegmental, length 150 mm, PCU/TAV-Eli, sterile

NFlex additional equipment for Pangea

03.600.403	Counter Torque Instrument for T25, short
03.620.022	Screwdriver Shaft Stardrive, T25, short, with Hexagonal Coupling
03.620.061	T-Handle with Ratchet Wrench and with Torque Limiter, 10 Nm
03.620.019	Torque-limiting Handle, 10 Nm, for Pangea (optional)

NFlex additional elements for Click'X

03.600.404	Rod Pusher/Counter Torque, short, keyed
03.600.427	Locking Cap Insertion Tube, for Click'X
03.620.022	Screwdriver Shaft Stardrive, T25, short, with Hexagonal Coupling
388.079	Screwdriver Shaft 3.5 mm, with Hexagonal Quick Coupling 6.0 mm
03.627.017	Torque-limiting Ratchet Handle, 7 Nm
321.133	Torque-limiting T-Handle, 7 Nm (optional)

Note: For additional information, please refer to the package insert.

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