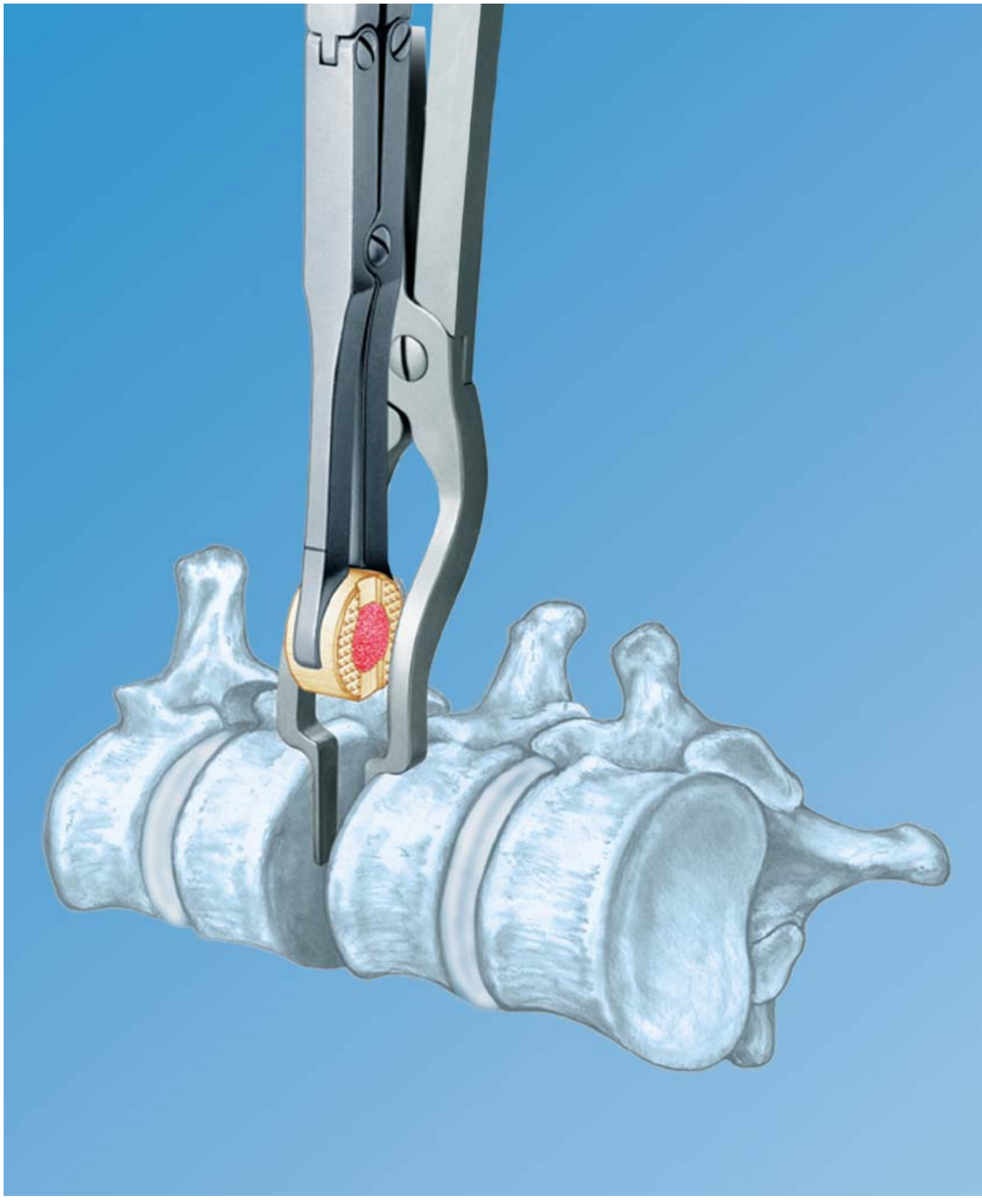
Spinal Correction FRA Spacer System.

For use with the Small Stature FRA Spacer and the FRA Spacer.

Technique Guide



SYNTHES® Spine

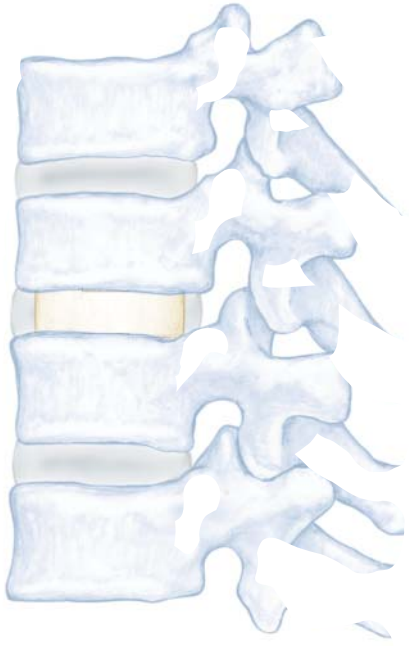
Instruments and implants approved by the AO Foundation

Table of Contents

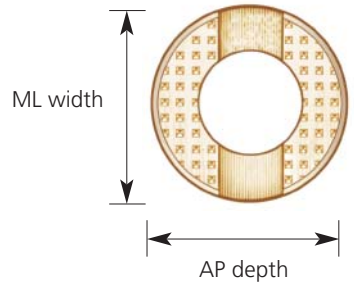
Image intensifier control

Spinal Correction FRA System

The Spinal Correction FRA System comprises instruments designed for use with the Small Stature FRA Spacer and the FRA Spacer for lumbar interbody fusion. The instruments facilitate lateral insertion of the allograft spacers. The spacers are designed to provide anterior column support in association with correction and spinal realignment. The spacers are available parallel or angled and in a range of heights.



Small Stature FRA Spacer

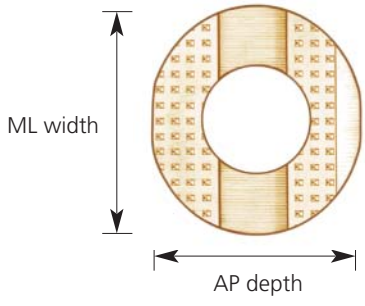


Top view

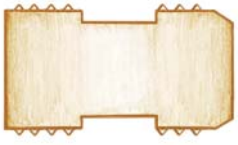
SS FRA
Parallel Spacer

SS FRA Angled
Lateral Spacer

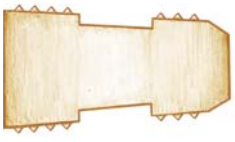
FRA Spacer



Top view



FRA
Parallel Spacer



FRA Angled
Lateral Spacer

Note: For full specification/dimensions please reference Spinal Correction FRA Spacer brochure.

Approach

The spinal correction FRA instruments are designed to facilitate distraction, sizing, and insertion of the Small Stature FRA Spacer or FRA Spacer for anterior column support during correction.

1

Approach

The spine is approached through a lateral or anterolateral incision at the appropriate level(s). Remove the disc and surrounding tissue necessary for anterior release.

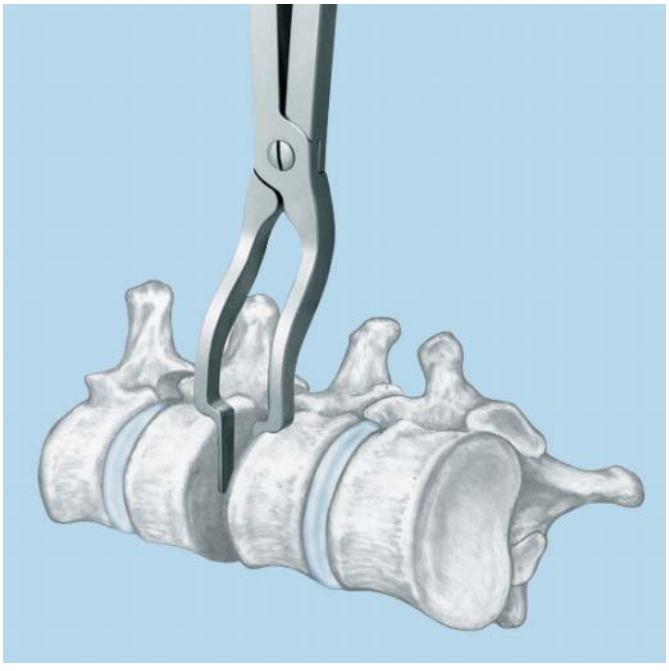
Determine which spacer type (Small Stature FRA Spacer or FRA Spacer) will best fit each spinal level. Estimate whether a parallel or angled spacer will best accommodate the spinal correction.

2
Distract

Instruments	
389.026	Curved Distractor, small
396.941	Curved Distractor

This technique describes the use of three (3) options for distracting the disc space; intervertebral distraction, pin distraction, and lateral distraction.

Intervertebral distraction
For intervertebral distraction, insert the small curved distractor (for SS FRA Spacer) or curved distractor (for FRA Spacer) into the disc space and distract. Tighten the speed nut on the handle to maintain distraction. Ensure that the distractor is held firmly in place.



2

Distract continued

Instruments	
389.029	Screwdriver for Schanz Screws
389.028	Pin Distractor

Pin distraction

For Schanz screw distraction, insert 5.0 mm Schanz screws laterally into the adjacent vertebral bodies, using the screwdriver for Schanz screws. Slide the sleeves of the pin distractor over the Schanz screws and distract. Tighten the speed nut on the handle to maintain distraction. Ensure that the distractor is held firmly in place.

Alternatively, the pin distractor may be used to distract between anterior fixation screws, such as USS or Small Stature USS screws, using the hook or screw holders. With the holders secured onto the desired screws, slide the sleeves of the pin distractor over the holders and distract. Tighten the speed nut on the handle to maintain distraction. Ensure that the distractor is held firmly in place.

Instruments

389.029	Screwdriver for Schanz Screws
397.084	Lateral Distractor
397.097	Distractor Insert for Universal Spinal System (USS)
397.098	Distractor Insert for Variable Axis System (VAS)
397.099	Distractor Insert for Click'X

Lateral distraction

Distraction may also be achieved by using the lateral distractor. The sleeves of the lateral distractor fit over the Schanz screws inserted into the vertebral bodies, or over the fixation screws using the appropriate distractor inserts (USS, VAS, or Click'X).

If Schanz screws are used, insert 5.0 mm Schanz screws using the screwdriver for Schanz screws. Slide the sleeves of the lateral distractor over the Schanz screws and distract using the distractor knob.

If fixation screws are used, place the insert corresponding to the screw (e.g. USS distractor insert) into each sleeve of the lateral distractor. Place the tips of the inserts over the screws and distract using the distractor knob.

Determine Implant Size

3

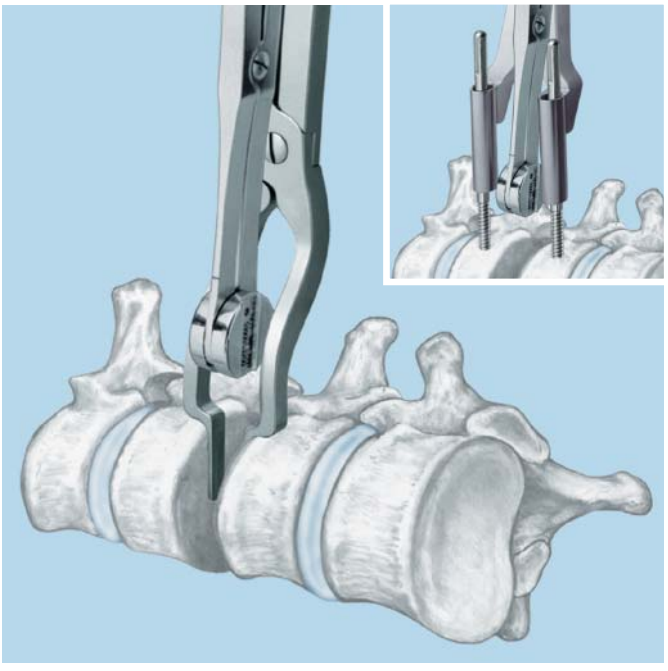
Determine implant size

Instruments	
389.049	Small Stature FRA Trial Spacer Handle
397.089	Trial Spacer Handle

Once the desired level of distraction (intervertebral, pin, or lateral) is achieved, determine the implant size using the SS FRA or FRA trial spacers. If using the SS FRA Spacer, connect an appropriately-sized SS FRA trial spacer to the SS FRA trial spacer handle and insert into the disc space.

If using the FRA spacer, connect an appropriately-sized FRA trial spacer to the trial spacer handle and insert into the disc space. If the trial spacer appears too loose or too tight, try the next size until a secure fit is achieved. Remove the trial spacer.

Select the implant corresponding to the correct trial spacer.



Insert Implant

4

Insert implant

Instruments	
389.049	Small Stature FRA Trial Spacer Handle
397.089	Trial Spacer Handle

Prior to insertion, refer to the implant package insert for preparation and handling instructions, including soaking for freeze-dried implants.

If using the SS FRA Spacer, secure the selected implant using either the SS FRA implant holder around the perimeter, or the SS FRA implant holder, slot, within the implant slots. If using the FRA Spacer, secure the selected FRA Spacer using the implant holder, slot. Tighten the speed nut on the handle to ensure that the implant is held securely.

SS FRA
implant holder

SS FRA
implant holder, slot

Insert Implant continued

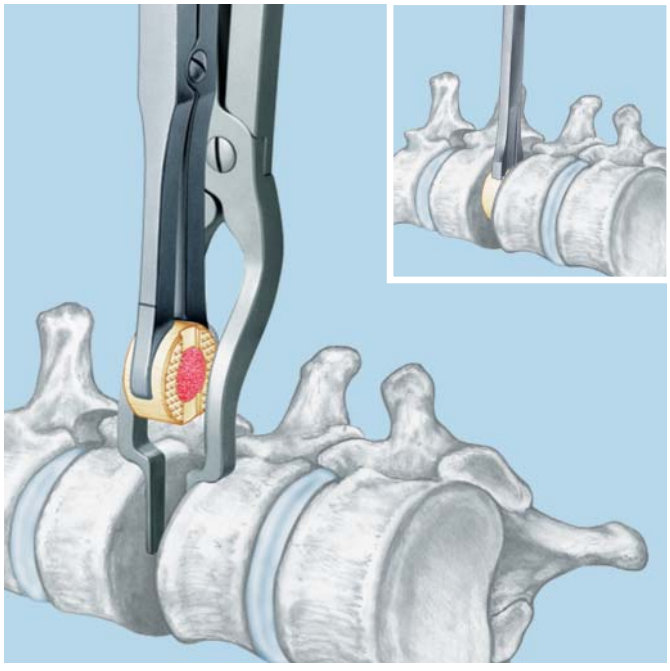
Instruments

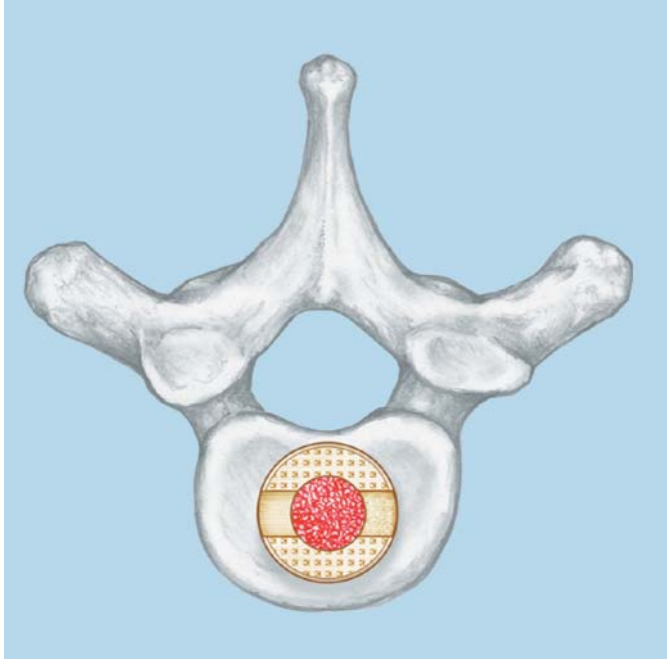
389.052	Small Stature FRA Impactor
397.023	Impactor, Crescent

The center of the implant may be filled with osteogenic or osteoconductive material. Introduce the implant in the correct orientation into the disc space.

Once the implant is in the desired position, remove the implant holder and distractor. If Schanz screws are used for distraction, remove at this time. Gentle impaction may be necessary to position the implant using the implant holder and, if necessary, the SS FRA impactor or (FRA) crescent impactor.

Important: Before use, ensure that the impactor fits flush against the implant. Do not forcibly strike the impactor when tapping the implant into position as this may cause the implant to break.





Instruments

294.53 5.0 mm Schanz Screws, 125 mm, blunted trocar point
- Schanz screws are inserted laterally into adjacent vertebral bodies using the screwdriver for Schanz screws

389.026 Curved Distractor, small
- Allows intervertebral distraction to open disc space
- Blades fit within SS FRA Spacer slots for simultaneous distraction and insertion

389.028 Pin Distractor
- Opens intervertebral space to facilitate implant insertion
- Distractor sleeves fit over the Schanz screws to allow distraction between vertebrae. They also fit over the hook or screw holders in the Universal Spinal System (USS) (388.61) and the Small Stature Universal Spinal System (SS USS) (388.612)

389.029 Screwdriver for Schanz Screws

389.037–
389.042 Small Stature FRA Trial Spacers, parallel
– 6 mm–11 mm heights

389.043–
389.048 Small Stature FRA Trial Spacers, angled
– 6 mm–11 mm heights

389.049 Small Stature FRA Trial Spacer Handle
– Trial spacers ensure accurate sizing and selection of SS FRA Spacers
– Heights match parallel and angled SS FRA Spacers
– All SS FRA trial spacers fit the small stature FRA trial spacer handle
– Taller side of angled trial spacer is indicated by an etched line

389.050 Small Stature FRA Implant Holder
– Securely grips the SS FRA Spacer perimeter for controlled insertion
– Fits between the blades of the distractor allowing simultaneous distraction and insertion
– Sturdy handle allows gentle impaction upon insertion

389.051 Small Stature FRA Implant Holder, slot
– Securely grips the FRA Spacer slots for controlled insertion
– Fits between the blades of the distractor allowing simultaneous distraction and insertion
– Sturdy handle allows gentle impaction upon insertion

389.052 Small Stature FRA Impactor
– Allows gentle impaction for final positioning of SS FRA Spacer
– Grooved surface prevents slipping

389.053–389.059 ALIF Trial Spacers, parallel
– 9 mm–21 mm heights

389.060–389.066 ALIF Trial Spacers, angled, lateral or anterior
– 9 mm–21 mm heights

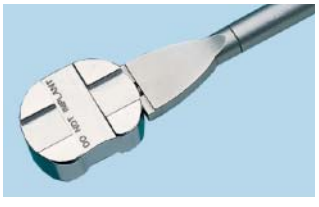
396.941 Curved Distractor
– Allows intervertebral distraction to open disc space
– Blades fit within FRA Spacer slots for simultaneous distraction and insertion

397.011 Implant Holder, slot
- Securely grips the FRA Spacer slots for controlled insertion
- Permits simultaneous distraction and insertion

397.023 Impactor, crescent
- Allows gentle impaction for final positioning of FRA Spacer
- Grooved surface prevents slipping

397.084 Lateral Distractor
- Opens disc space to facilitate implant insertion
- Lateral distractor sleeves slide over Schanz screws to allow intervertebral distraction
- Optional distractor inserts fit into distractor sleeves, allowing engagement of the appropriate fixation screwhead

397.089 Trial Spacer Handle
- Trial spacers ensure accurate sizing and selection of FRA Spacers
- Heights match parallel and angled FRA Spacers
- All ALIF trial spacers fit the trial spacer handle
- Taller side of trial spacer is indicated by an etched line



397.097	Distractor Insert, for Universal Spinal System (USS) – 2 required	
397.098	Distractor Insert, for Variable Axis System (VAS) – 2 required	
397.099	Distractor Insert, for Click'X – 2 required	

Spinal Correction FRA System Instrument Set (105.772)

Graphic Case

690.026	Spinal Correction FRA Graphic Case

Instruments

294.53	5.0 mm Schanz Screw, blunted trocar point, 125 mm, 2 ea.
389.026	Curved Distractor, small
389.028	Pin Distractor
389.029	Screwdriver, for Schanz Screws
389.049	Small Stature FRA Trial Spacer Handle
389.050	Small Stature FRA Implant Holder
389.051	Small Stature FRA Implant Holder, slot
389.052	Small Stature FRA Impactor
396.941	Curved Distractor
397.011	Implant Holder, slot
397.023	Impactor, Crescent
397.084	Lateral Distractor
397.089	Trial Spacer Handle
397.097	Distractor Insert for Universal Spinal System (USS), 2 ea.
397.098	Distractor Insert for Variable Axis System (VAS), 2 ea.
397.099	Distractor Insert for Click'X, 2 ea.

Small Stature FRA Trial Spacers

Parallel	Angled	Height
389.037	389.043	6 mm
389.038	389.044	7 mm
389.039	389.045	8 mm
389.040	389.046	9 mm
389.041	389.047	10 mm
389.042	389.048	11 mm

ALIF Trial Spacers

Parallel	Angled, lateral or anterior	Height
389.053	389.060	9 mm
389.054	389.061	11 mm
389.055	389.062	13 mm
389.056	389.063	15 mm
389.057	389.064	17 mm
389.058	389.065	19 mm
389.059	389.066	21 mm

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

For detailed cleaning and sterilization instructions, please refer to http://us.synthes.com/Medical+Community/Cleaning+and+Sterilization.htm or to the below listed inserts, which will be included in the shipping container:
—Processing Synthes Reusable Medical Devices—Instruments, Instrument Trays and Graphic Cases—DJ1305
—Processing Non-sterile Synthes Implants—DJ1304

Also Available

389.077	Spinal Correction ACF Trial Spacer Handle
389.078	Spinal Correction ACF Extended Implant Holder
389.079	Impactor, small, extended

Spinal Correction ACF Detachable Trial Spacers

389.081–389.088	Parallel, 5 mm–12 mm heights
389.091–389.098	Lordotic, 5 mm–12 mm heights

SYNTHES® Spine

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