Hybrid Anterior Cervical Plating System Surgical Technique





Aesculap Spine



### Content \_\_\_\_\_

Α	System Overview – Hybrid solution	3
	Design Advantages	
	Indications	
	Implant Information	
В	Surgical Technique	8
С	Implant Overview and Sets	24
	Hybrid Set 1-3 Level	
	4-5 Level complementary implant set	
D	Instrument Overview and Set	30

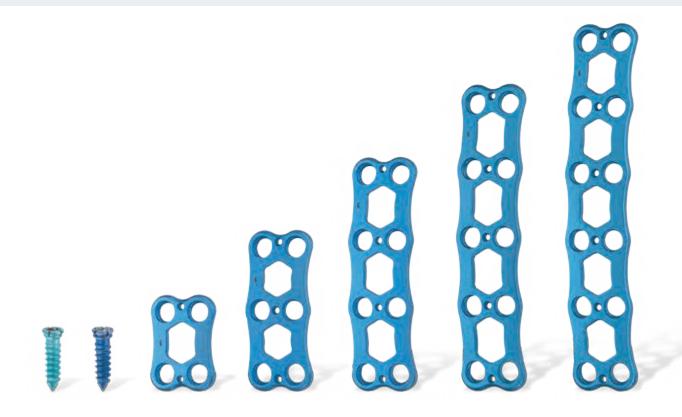


The Quintex® hybrid cervical plating system offers distinct implant combinations. Implant components can be combined to accommodate patient-specific clinical and anatomical considerations. With only one instrument set all construct options can be formed according to the course of disease.

Applying hybrid constructs addressing each level of the patient's cervical spine individually is possible.

#### **System Features**

- 2 construct options: constrained, semicontrained in addition to mixed hybrid options.
- Plates with generous graft window
- Low profile plate (2 mm)
- Self-drilling and self-tapping screws
- Fully automatic locking mechanism
- Color coded implants
- Intuitive instruments





### System Overview - Hybrid solution

#### Quintex® Design Advantages - Hybrid Solution

#### ■ High Variability

Choice of constrained, semi-constrained and hybrid construct options.

#### I Thin Plate Design

2 mm low profile implant

#### **■** Excellent Visibility

The graft window helps to control the interbody fusion device

#### Automatic Locking

Integrated screw locking mechanism

#### ■ Self-drilling and Self-tapping Screws

Improved screw tip and thread configuration for easy start and insertion

#### ■ Strong Tactile Feel

Very firm connection between screw and screwdriver

#### ■ One Intuitive Instrument Set

Easy preparation and implant insertion

#### Indications

Surgical implants serve to support normal healing processes. They are not intended to either replace normal structures of the human body or permanently bear the loads they would be subjected to in cases of incomplete healing.

Use for the following indications:

- Degenerative disc disease
- Trauma (including fractures or dislocation)
- Post-traumatic kyphosis or lordosis
- Tumors
- Spondylolisthesis

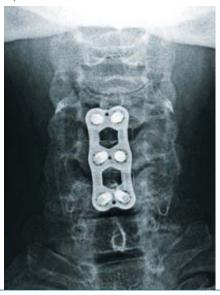
- Spinal Stenosis
- Deformity (Scoliosis, Kyphosis, and / or Lordosis)
- Pseudarthrosis following an unsuccessful spinal operation
- Symptomatic cervical spondylosis
- Instability following surgical intervention due to the indications listed above
- Reoperations necessitated by prior fusion failure

For these indications, screws can be fixated in the region C2 to T1.

#### Note:

For further information please see instructions for use TA013366 Quintex® Implants and TA013377 Quintex® Instruments

#### Hybrid Plate



# A

### System Overview - Hybrid solution

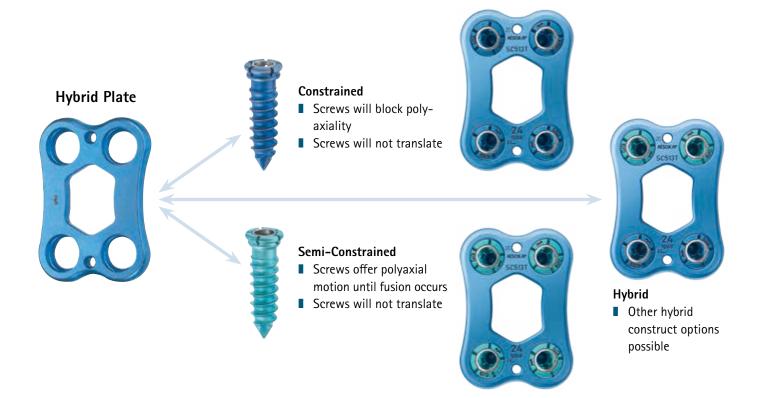
#### **Implant Information**

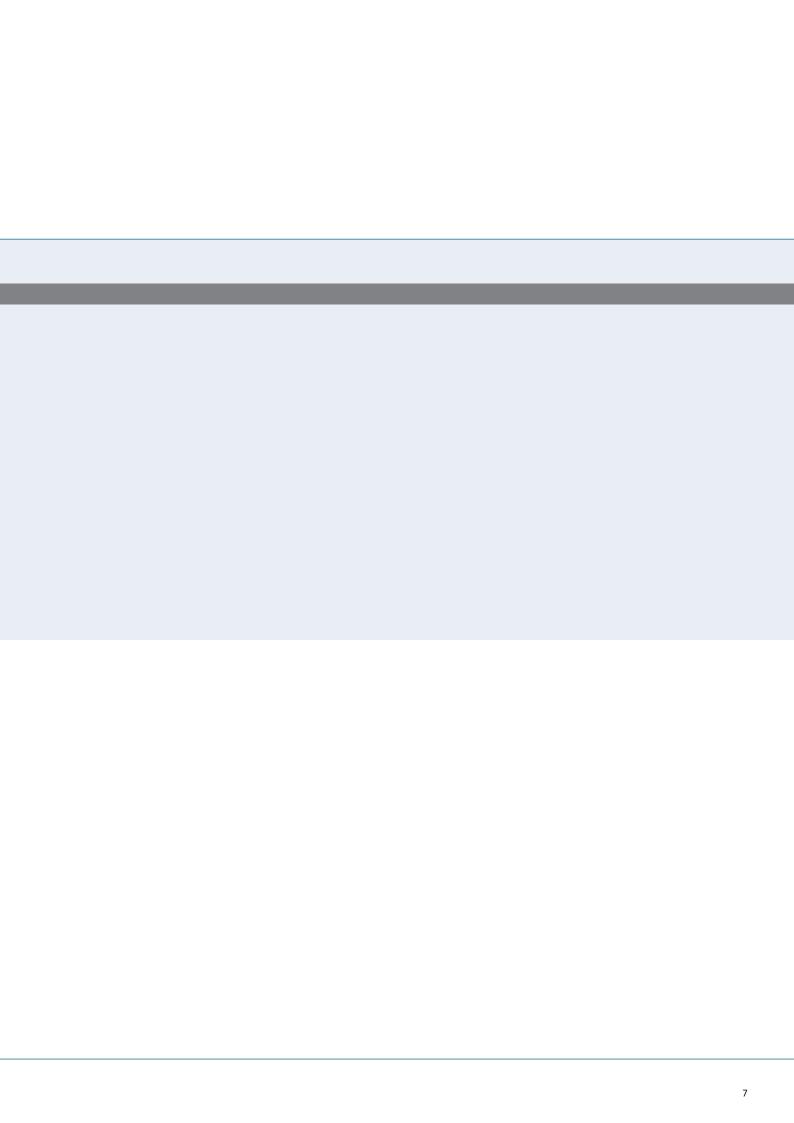
The Quintex® hybrid system is used for anterior mono- and multisegmental stabilization of the cervical spine.

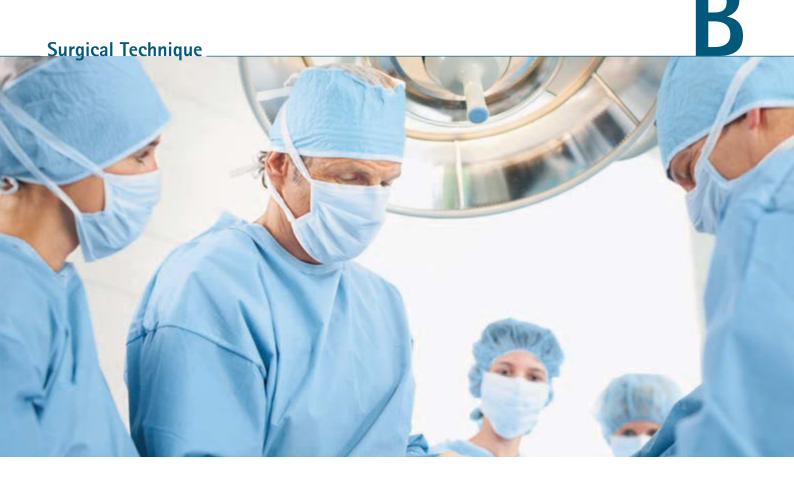
The hybrid system consists of the following components:

- Hybrid cervical plate constrained and semi-constrained
- Constrained bone screw
  (10-18 mm, diameter 4.0 mm/
  11-19 mm, diameter 4.5 mm)
- Semi-constrained bone screw (10-18 mm, diameter 4.0 mm/ 11-19 mm, diameter 4.5 mm)

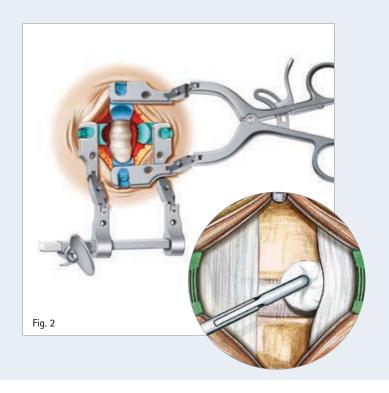
Specific instruments are available and must be used for implanting these components.











#### Patient Positioning (Fig. 1)

The patient is placed in the supine position with the head slightly reclined and resting in a headrest or ring.

Once the lordotic spine has been supported, the interscapular region may be bolstered to emphasize the reclination of the cervical spine (Fig. 1).

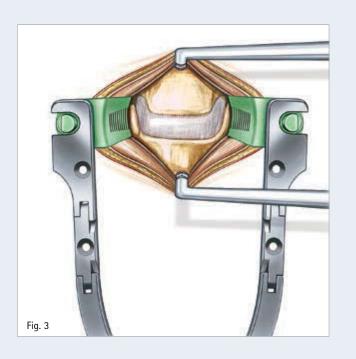
■ The arms are fixed along the sides of the body. Using the arm fixations, draw the shoulders down far enough to remove them from the radiation path of the segment to be fused.

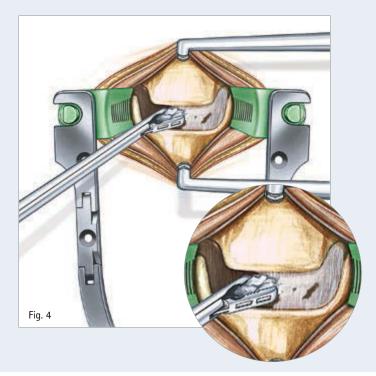
#### Exposure of the Intervertebral Space (Fig. 2)

- After the skin incision and preparation, the CASPAR Cervical Retractor is applied (Fig. 2). The blades are available in PEEK and Titanium. A counter retractor can be used. The subcutaneous tissue is separated from the platysma cranially, caudally and medially, and the platysma is also separated following the direction of its fibers. The margins of the platysma can be held apart with the retractor or with two surgical forceps.
- Now the medial edge of the sternocleidomastoid muscle is located and prepared with the index finger in the connective tissue space over the ventral surface of the cervical spine and under lateralization of the vascular nerve bundle and medialization of the trachea, esophagus and thyroid gland.
- After the Langenbeck hooks have been inserted, the ventral surface of the cervical spine, still covered by a thin prevertebral layer of connective tissue, is revealed. This layer can now be exposed by either a blunt scissor or alternatively through bipolar coagulation in order to expand the tissue cranially and caudally using a swab. A k-wire can be set under X-ray monitoring to mark the intervertebral disc space.

B

### Surgical Technique

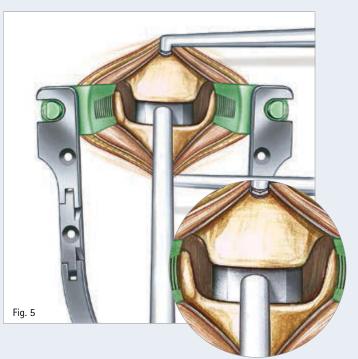


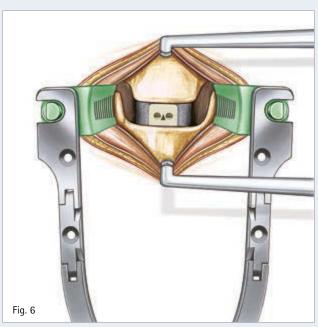


## Distraction/Discectomy/Preparation of the Endplates (Fig. 3-4)

- The distraction screws are placed in position and the CASPAR distractor is applied following the CASPAR technique (Fig. 3).
- Complete discectomy is performed using various rongeurs, box curettes and bone curettes (Fig. 4). While using a high speed drill to remove dorsal ostephytes, care must be taken to avoid damaging the vertebral body endplates.

**Note:** Excessive preparation of the endplates may weaken the construct and cause subsidence of the interbody device.





#### Insertion of Interbody Device (Fig. 5-6)

- Bone graft or interbody devices made of Titanium, PEEK or titanium coated PEEK spacers can be used, e.g. CeSPACE®XP.
- The correct size of CeSPACE® can be determined using the trial implants (Fig. 5).
- CeSPACE® has different implant shapes. Therefore different trials are available for the respective system. Laser markings on the handle as well as the trial itself indicate the cranial and caudal side of the trial.

#### Determination of implant size of CeSPACE® Titanium

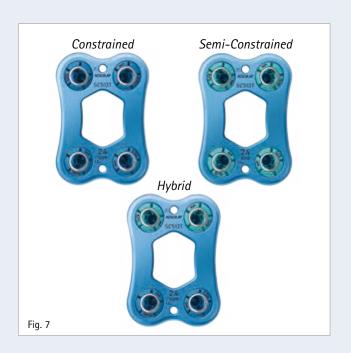
The height of the CeSPACE® Titanium trials corresponds with the height of the final implant and includes the fixation crown.

## Determination of implant size of CeSPACE $^{\circ}$ PEEK and CeSPACE $^{\circ}$ XP

The CeSPACE® PEEK and CeSPACE® trials mimic the anatomical shape of the corresponding anatomically shaped implant.

■ The CeSPACE® implant should be inserted centrally in AP direction leaving a distance of approximately 1–2 mm to both the anterior and posterior rim (Fig. 6).

### **Surgical Technique**





#### Plate Selection and Length Verification (Fig. 7-8)

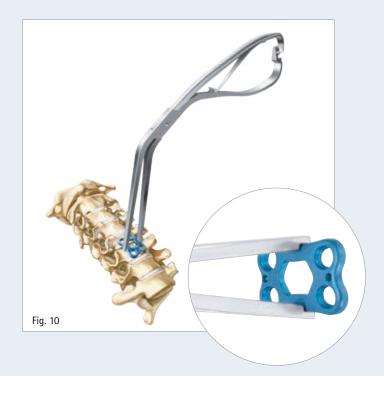
The Quintex® hybrid system is designed with the patient and surgeon in mind. Its constrained, semi-constrained and hybrid construct options offer intraoperative versatility and accommodate a wide range of anatomical considerations (Fig. 7). Once the desired plating construct has been selected, the Caliper (SC421R) may be used to provide a linear measurement of the plate length (Fig. 8).

**Note:** Hybrid plates should be sized to encompass the desired area of fixation.

#### Note:

- For a successful treatment the proper selection of implant size, shape and design should be considered. Quintex® system implants are not intended to either replace normal structures of the human body or permanently bear the loads they would be subjected to in case of incomplete healing. The indication of a cervical plate therefore is combined with an indication of an interbody fusion or vertebral body replacement device.
- Intraoperative contamination with blood, secretions or other fluids may render the contaminated component unsuitable for resterilization!





#### Plate Contouring (Fig. 9a and 9b)

Quintex® plates are pre-contoured to approximate cervical lordotic anatomy. If additional contouring is required, the plate bender (SC420R) should be used. The bending zone is the area between the pairs of holes within the bone graft window (window in the plate).

#### Adding Lordosis:

■ To increase the lordosis, place the Quintex® plate with the bending zone positioned centrally between the two upper rolls of the plate bender (Fig. 9a).

#### Decreasing Lordosis:

To decrease the lordosis, place the bending wedge over the bending zone (Fig. 9b).

**Note:** The area on the instrument on which the lordosis of the plate can be reduced is labeled 'STRAIGHTEN PLATE HERE'.

**Note:** In order to prevent excessive or insufficient lordosis, the long Quintex® plates should be bent in steps (one bending zone after another on multi-level plates).

#### **Caution:**

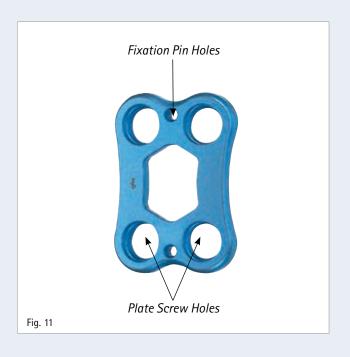
- Contouring of the plate should be minimized as excessive contouring can fatigue implant materials.
- Always bend the Quintex® plate in one direction only. Do not bend back the Quintex® plate.
- Always bend the plate only in the zone where the graft window is located. Never bend the plate close to or over the screw holes.

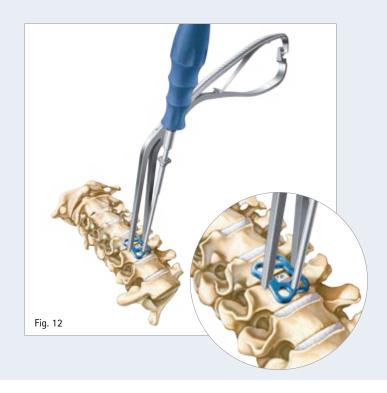
#### Plate Insertion (Fig. 10)

The Quintex® system features a plate holder (SC434R) to facilitate handling.

- Use the plate holder forceps to grasp the Quintex® plate by the outer edge, see Fig. 10.
- Compress the handles of the plate holding forceps to activate the lock. The plate holding forceps now holds the Quintex® plate without further pressure required on the handles.
- As soon as the Quintex® plate is correctly positioned, fix the plate with fixation pins and further press the handles of the plate holding forceps to release the lock.

### **Surgical Technique**





#### Temporary Plate Fixation (Fig. 11-12)

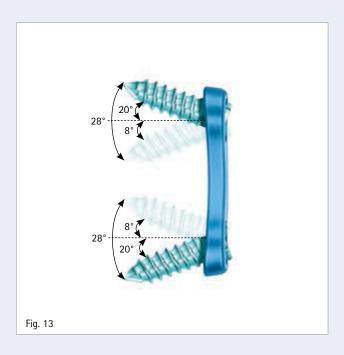
#### Inserting the Plate Fixation Pins:

- Fixation pins must be used to provide temporary fixation of Quintex® plates to the vertebral bodies. Temporary fixation prevents unintended repositioning of the plate during screw hole preparation and screw placement.
- Load one fixation pin (FJ833RS) into the fixation pin instrument (SC422R). To do this, pull back the outer sleeve of the instrument and insert the fixation pin. To secure the fixation pin in the instrument release outer sleeve. The outer sleeve is then pushed forward by a spring.
- Place the plate in the desired position and insert the fixation pin into the vertebral body through the pin hole (Fig. 11) by gently advancing the instrument until the pin is fully seated.
- To release the fixation pin from the instrument pull back outer sleeve fully and remove the instrument from the pin.
- Repeat this process for each level where fixation pin placement is desired. At a minimum, the most cranial and caudal fixation pin holes of the plate are utilized for temporary fixation of the plate (Fig. 12).

**Note:** At least two fixation pins must be inserted for a secure fixation of the Quintex® plate. Use the instrument for fixation pins (SC422R) for inserting and removing the pins!

#### Removing the Plate Fixation Pins:

- Fixation pins are removed after screw placement
- The instrument for fixation pins (SC422R) is also used for pin removal
- Attach the instrument onto the fixation pin
- To do this, pull back the outer sleeve of the instrument
- To secure the fixation pin release the outer sleeve of the instrument
- The outer sleeve is then pushed forward by a spring mechanism
- Pull the fixation pin out of the vertebral body
- To release the fixation pin from the instrument pull back the outer sleeve fully and take out the fixation pin from the instrument



#### Angulation (Fig. 13)

The screw insertion angle can be adjusted in a cranial-caudal direction and in a medial-lateral direction when using a single drill guide or cortical center punch.

The Quintex $^{\circ}$  hybrid plate has a maximum angulation of up to  $+20^{\circ}/-8^{\circ}$  in the distal holes (Fig. 13) and  $+15^{\circ}/-15^{\circ}$  in the medial holes of the multilevel plate.

The medial/lateral angulation is up to  $6^{\circ}\mbox{/-}6^{\circ}$  in all holes of the plate.

### **Surgical Technique**



#### Opening the Cortex (Fig. 14 and Fig. 15)

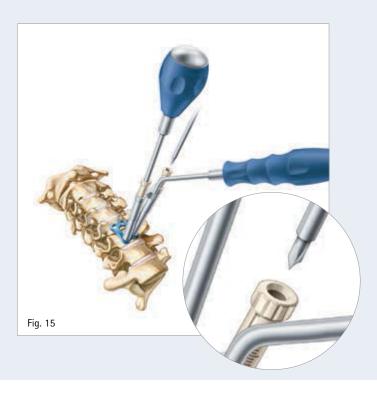
Quintex® provides three possibilities to open up the cortical bone layer of the vertebral body. The holes for the self-drilling and self-tapping Quintex® screws are prepared using either the self-centering cortical punch, cortical punch through drill guide or the drill in combination with a drill guide. Commonly, the screw can be screwed in without drilling.

- Gently pierce the anterior cortex of the vertebral body by advancing the cortical punch into bone until stop is met.
   The cortical punch features a positive stop at a depth of 6 mm.
- Repeat for the contralateral side and any remaining screw holes.

#### Cortical Punch with Self-Centring Sleeve (Fig. 14)

The cortical punch (SC428R) can be used as a stand-alone instrument. If used without guide the instrument must be assembled with the self-centring sleeve for appropriate pilot hole placement.

Position the cortical punch with sleeve to the desired angle and visually confirm that the trajectory is within the system's specified angulation.



#### Cortical Punch with Drill Guide (Fig. 15)

The cortical punch can be used without outersleeve in combination with a drill guide:

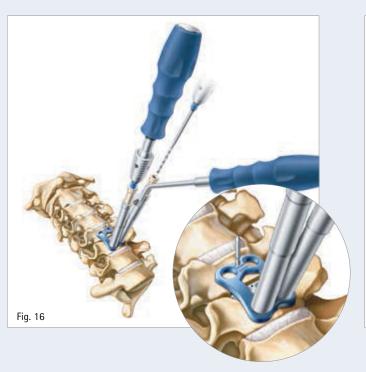
- Turn threaded cap counterclockwise to remove the outer sleeve from the threaded cap. Remove the self-centring outer sleeve of the cortical punch.
- Insert the cortical punch (without outer sleeve) into the drill guide.
- Position the drill guide to the desired angle on the prefixated plate and check visually that the trajectory is within the system's specified angulation.

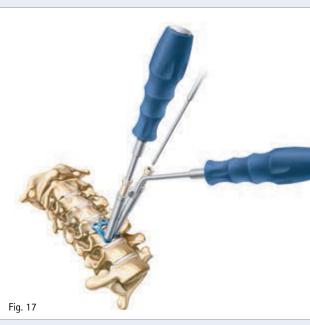
**Note:** Use of a cortical punch in combination with drill guide or self-centring sleeve is required to achieve appropriate placement of the screw holes.

The maximum penetration depth of the cortical punch with mounted outer sleeve is 6 mm.

The maximum penetration depth of the cortical punch through the drill guide is 6 mm to the shoulder between distal tip with trocar and the shaft. This shoulder will act as a stop on the cortical bone.

### **Surgical Technique**





#### Drilling and Tapping (optional Fig. 16 and Fig. 17)

The Quintex® system offers several drill guides to facilitate screw hole preparation and screw placement.

**Note:** Use of a drill guide or self centering sleeve is required to achieve appropriate placement of the screw holes.

#### **Guide Selection**

- The adjustable single drill guide (SC423R) and adjustable double drill guide (SC424R) accommodate all of the screw hole preparation instruments with a variable depth setting.
- The fixed single drill guide (SC425R) and fixed double drill guide (SC426R) accommodate all of the screw hole preparation instruments with a fixed depth of 14 mm.
- The Cortical Punch (SC428R) without self centering sleeve can be used through all of these drill guides.

**Note:** The fixed single drill guide and the fixed double drill guide are labeled '14 mm' on the sleeve for easier identification. The adjustable drill guides are equipped with adjustable depth stops. With every half turn (= depth adjustment by 0.5 mm) you will hear and feel the guide sleeve clicking into position. The thread in the drill guide is a left-hand thread.

#### **Drilling (optional Fig. 16)**

- Attach the drill bit (SC430R) to the drill handle (SC429R or SC436R).
- Alternatively attach the drill bit to a powered intrahandpiece (e.g. Aesculap® micro-Line handpiece GD450M/ GD456M).
- Select the desired guide and, if necessary, set the depth by rotating the adjustable stop(s) to the desired depth.
- Insert the drill into the drill guide and check depth with caliper or ruler (e.g. 14 mm).
- Position the drill guide to the desired angle on the pre-fixed plate and check visually that the trajectory is within the system's specified angulation.
- Slowly advance the drill bit through the lumen of the guide until the stop is reached.
- Repeat for the contralateral side and any remaining screw holes.

#### Tapping (optional Fig. 17)

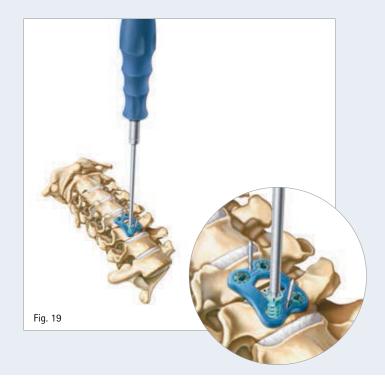
- Slowly advance the Tap (SC431R) through the lumen of the guide until the desired depth is tapped and/or the stop is reached.
- Repeat for the contralateral side and any remaining screw holes.

**Note:** The Quintex® system screws are self-drilling and drilling is commonly not required if a cortical punch is used. Quintex® system screws are self-tapping and manual tapping is commonly not required.

For hard bone always use the Quintex® drill and the Quintex® tap.

### **Surgical Technique**





#### Screw Selection (Fig. 18)

- Construct selection will determine the bone screw styles required to achieve the desired performance characteristics. For the Quintex® hybrid solution the following screws are available:
  - Constrained screws (blue)
  - Semi-constrained screws (green)
- The screw length can be verified by the measuring scale at the caddy.

#### Screw Placement (Fig. 19)

The Quintex® screws are loaded from the screw caddy.

- Load the desired screw onto the screwdriver (SC432R) by inserting the working end of the screwdriver into the head of the screw. Ensure that the screwdriver is fully seated into the screw then apply axial downward pressure to load the screw (Fig. 20).
- Make sure that the screwdriver holds the screw (self-holding feature).
- Align the tip of the screw with the screw hole on the vertebral body and angle the screw/driver assembly at the desired trajectory. Visually confirm that the trajectory is within the system's specified angulation. If the hole has been predrilled, approximate the pre-drilled trajectory.
- Gently but firmly advance the screw into the vertebral body by applying mild axial pressure with the screwdriver while rotating clockwise until resistance is met and the screw head fully engages in the hole.
- Remove the screwdriver from the screw head.
- Repeat for the contralateral side and any remaining screw holes.



#### Caution:

- The Quintex® plate and/or Quintex® screw may be damaged when screwing in the plate if the screwdriver is applied incorrectly!
- Insert the working end of the screwdriver fully into the hexalobe (receptive part) of the screw.
- When screwing in the screw, maintain a mild axial pressure on the screw.
- Applying the screwdriver at a slant or tilted would result in damage to the locking ring or locking mechanism of the Quintex\* screw, or may destruct the working end of the screwdriver.
- Always align the screwdriver with the axis of the screw.
- The Quintex® screw may be damaged or insufficiently locked if it is not correctly engaged in the hold of the Quintex® plate.
- Ensure that the Quintex® screw correctly engages in the hole of the Quintex® plate.
- The Quintex® screw must not be screwed in too deep.

### **Surgical Technique**



#### Screw Locking Confirmation (Fig. 21)

Make sure that the Quintex® screw is securely locked in the Quintex® plate.

- After removing the screwdriver, the locking ring of the screw must be flush with the screw head.
- Visually confirm screw/plate engagement by verifying that at least 3 petals of the screw head are located below the ventral surface of the plate's hole and that the lateral aspects of the screw are contained in the holes of the plate (Fig. 21).
- Visually confirm lock engagement for all screws in the same manner by visually noting that the locking ring is flush with the screw head.

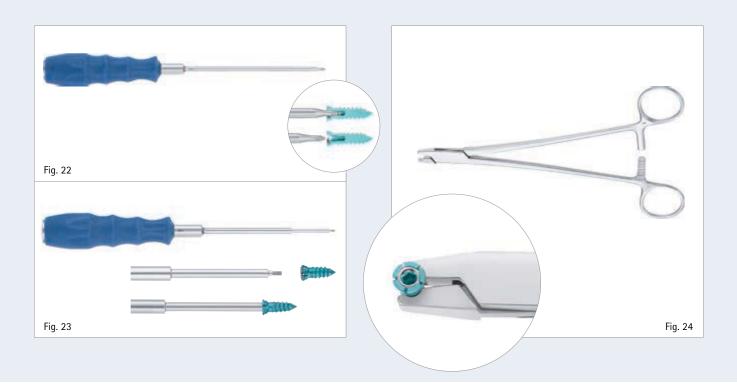
**Note:** The screw is securely locked when at least 3 of the 5 petals of the screw head are positioned in the hole of the Quintex® plate under the plate surface and both sides of the screw head are positioned in the hole underneath the plate surface from a lateral perspective.

**Practical tip:** Check if the Quintex® screw is correctly seated in the hole of the Quintex® plate:

If the Quintex® screw has not been fully screwed into the plate hole, screw the screw in deeper by 1/4 to 1/2 turns clockwise. If the Quintex® screw has been screwed in too deep, turn the screw by 1/4 to 1/2 turns counterclockwise.

#### Final Steps

- Remove all fixation pins as described on page 14.
- It is recommended to confirm acceptable implant placement using fluoroscopy or intraoperative radiographs.



#### Implant Removal (Fig. 22, Fig. 23, Fig. 24)

If necessary, Quintex® screws and plates can be removed.

- Carefully clear the anterior surface of the plate and screw head of any tissue overgrowth.
- Remove all screws with the screwdriver or in case of free spinning screws with the screw removal tool.
- Once all screws are removed, the plate can be removed.

#### Screw Removal with the Screwdriver

Try the regular screwdriver (SC432R, Fig. 22) to remove the screw.

- To remove an implanted Quintex® screw, insert the tip of the screwdriver fully into the screw head.
- When unscrewing the Quintex® screw with the screwdriver maintain a mild axial pressure on the screw.
- Turn the screwdriver counterclockwise to release the Quintex® screw.

#### Removal of Free-spinning Screws with the Screw Removal Tool

If the screw head of the free turning Quintex® screw does not automatically snap out of the hole in the Quintex® plate use the screw removal tool (SC433R, Fig. 23) instead of the screwdriver.

- Insert the screw removal tool as deep as possible into the screw head (Fig. 23).
- Turn the left-hand thread on the tip of the screw removal tool counterclockwise into the screw head as far as possible (The screw head has an internal threaded portion).
- Quintex\* screw is removed from the hole of the Quintex\* plate by pulling and turning the instrument counterclockwise at the same time.
- If you encounter difficulties removing the Quintex® screw from the screw removal tool use the holding forceps (FW076R, Fig. 24) as a counter torque.

**Note:** Using the screw removal tool damages the screw's locking ring. Implants removed using the screw removal tool should not be reused. The thread on the tip of the screw extraction instrument is a left-hand.

#### **Revision Tips**

- 4.5 mm screws are provided to accommodate revisiting a previously used screw hole.
- Do not reuse explanted implants.

C

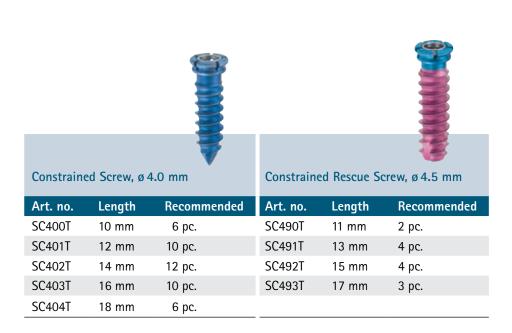
Implant Overview and Sets \_\_\_\_

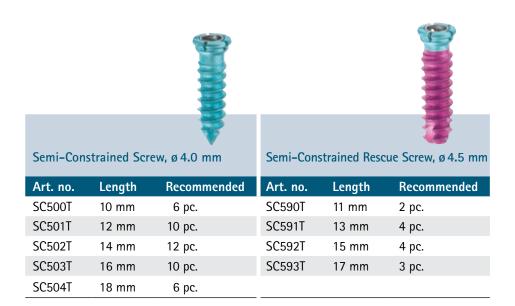
Quintex® Hybrid Set 1-3 Level

*Implants* 



Note: 4-5 Level Hybrid Plates can be found on page 28.





C

## Implant Overview and Sets \_\_\_\_\_

### Quintex® Hybrid Set 1-3 Level

### Trays and Caddies (Implants not included)

Art. no.	Description	Recommended
SC455R	Quintex® hybrid implant tray 1–3 level	1 pc.
JH217R	1/1 size wide perf. basket lid 489 x 257 mm	1 pc.
ME250P	Quintex® screw caddy lid constrained D 4.0 mm	1 pc.
ME251P	Quintex® screw caddy lid constrained D 4.5 mm	1 pc.
ME544P	Quintex® constrained screw caddy base	1 pc.
ME254P	Quintex® screw caddy lid semi-constrained D 4.0 mm	1 pc.
ME255P	Quintex® screw caddy lid semi-constrained D 4.5 mm	1 pc.
ME543P	Quintex® semi-constrained screw caddy base	1 pc.
ME263P	Quintex® hybrid plate caddy lid 1-level	1 pc.
ME264P	Quintex® hybrid plate caddy lid 2-level	1 pc.
ME265P	Quintex® hybrid plate caddy lid 3-level	1 pc.
ME538P	Quintex® hybrid plate caddy base 1-level	1 pc.
ME539P	Quintex® hybrid plate caddy base 2-level	1 pc.
ME540P	Quintex® hybrid plate caddy base 3-level	1 pc.
TF054	Packing stencil for SC455R	1 pc.
JK442	Container	1 pc.
JK489	Container lid	1 pc.

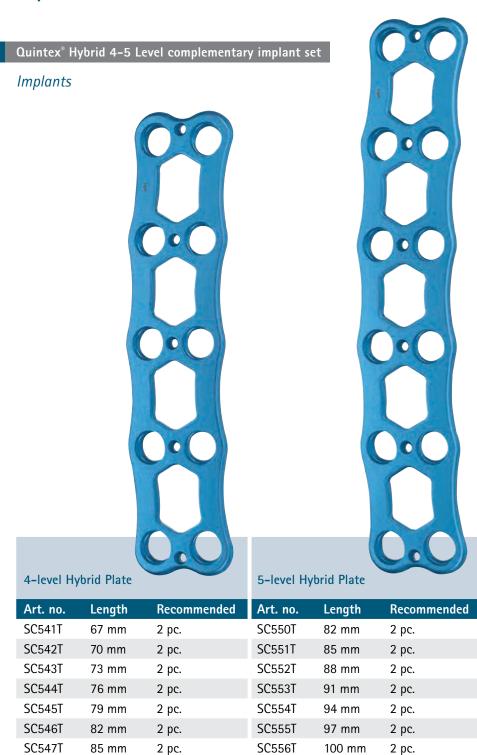
## Hybrid Implant Tray and Caddies (Implants not included)





C

### Implant Overview and Sets \_



SC557T

103 mm

2 pc.

## Tray and Caddies (Implants not included)

Art. no.	Description	Recommended
SC454R	Quintex® implant tray 4–5 level	1 pc.
JH217R	1/1 size wide perf. basket lid 489 x 257 mm	1 pc.
ME266P	Quintex® hybrid plate caddy lid 4-level	1 pc.
ME267P	Quintex® hybrid plate caddy lid 5-level	1 pc.
ME541P	Quintex® hybrid plate caddy base 4-level	1 pc.
ME542P	Quintex® hybrid plate caddy base 5-level	1 pc.
TF053	Packing stencil for SC454R	1 pc.
JK489	Container lid	1 pc.
JK440	Container	1 pc.

## 4–5 Level complementary implant tray (Implants not included)



D

## Instrument Overview and Set \_\_\_\_\_

#### *Instruments*

	Art. no.	Description	Recommended	Optional
250	SC420R	Quintex® plate bender	1 pc.	
	SC421R	Quintex® caliper	1 pc.	
	SC422R	Quintex® fixation pin instrument	1 pc.	
	FJ833RS	ABC and Quintex® plate fixation pin single sterile	6 pc.	
	SC423R	Quintex® adjustable single drill guide	1 pc.	
	SC424R	Quintex® adjustable double drill guide	1 pc.	
	SC428R	Quintex® cortical punch D 2.7 x 6 mm	1 pc.	
	SC429R	Quintex® drill handle	1 pc.	
	SC436R	Quintex <sup>®</sup> drill handle tear drop style		1 pc.

Art. no.	Description	Recommended	Optional
SC430R	Quintex® drill bit D 2.9 mm nonsterile	2 pc.	
SC431R	Quintex® tap D 4.0 mm	1 pc.	
SC432R	Quintex® screwdriver	2 pc.	
SC433R	Quintex® screw removal tool	1 pc.	
SC434R	Quintex® plate holder	1 pc.	
FW076R	S4°C rod holding forceps to remove screw from removal tool	1 pc.	
SC425R	Quintex® fixed single drill guide 14 mm		1 pc.
SC426R	Quintex® fixed double drill guide 14 mm		1 pc.

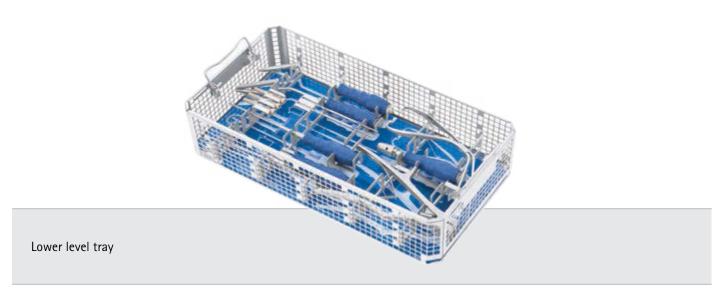
### Instrument Overview and Set \_\_\_\_\_

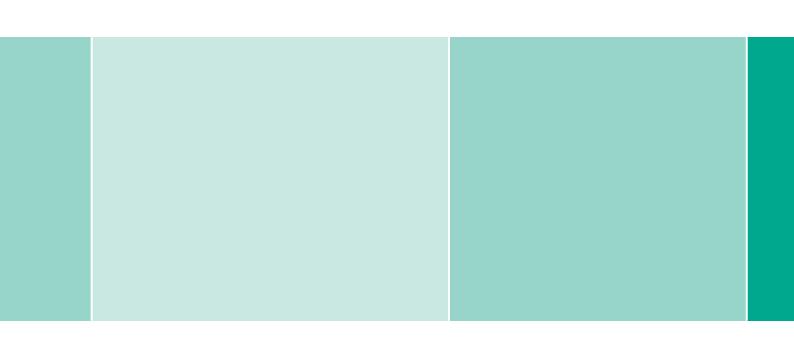
### Instrument Tray (Instruments not included)

Art. no.	Description	Recommended
SC451R	Quintex® instrument tray	1 pc.
JH217R	1/1 size wide perforated basket lid 489 x 257 mm	1 pc.
TF050	Graphic template for SC451R	1 pc.
TF051	Packing stencil for SC451R	1 pc.
JK442	Container	1 pc.
JK489	Container lid	1 pc.

## Instrument Tray (Instruments not included)







The main product trademark 'Aesculap' and the product trademarks 'CeSPACE', 'Quintex' and 'S4' are registered trademarks of Aesculap AG.

Subject to technical changes. All rights reserved. This brochure may only be used for the exclusive purpose of obtaining information about our products. Reproduction in any form partial or otherwise is not permitted.