ST/29E-2

ChM®

CERVICAL LOCKING PLATE

- *IMPLANTS*
- *INSTRUMENT SET 40.4820.700*
- *SURGICAL TECHNIQUE*

www.chm.eu

SYMBOLS DESCRIPTIONS

Ti	Titanium or titanium alloy		Self-tapping
Len	Length		Self-drilling
	Torx drive	Ster Non Ster	Available in sterile/ non- sterile condition
	Diameter		See surgery technique
	Recommended length range for a particular nail		

	Caution - pay attention to a special procedure.
	Perform the activity under X-Ray control.
	Information about the next stages of a procedure.
	Proceed to the next stage.
	Return to the specified stage and repeat the activity.
	Before using the product, carefully read the Instructions for Use. It contains, among others, indications, contraindications, side effects, recommendations and warnings related to the use of the product.
	The above description is not a detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

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The manufacturer reserves the right to introduce design changes.
Updated INSTRUCTIONS FOR USE are available at the following website: ifu.chm.eu

1. INTRODUCTION

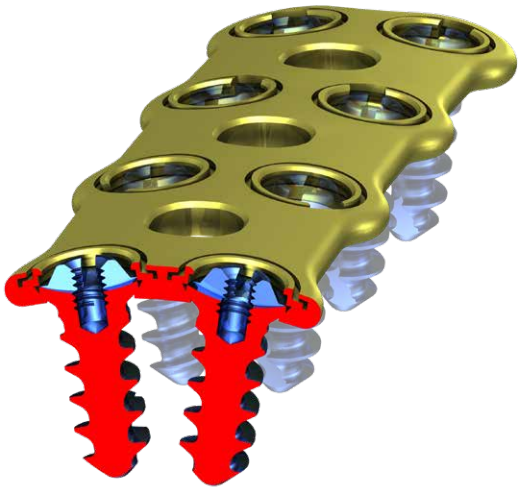
The cervical locking plates system is intended for the treatment of the cervical spine using an anterior surgical approach.
The system includes locking cervical plates and screws and a set of instruments necessary for implants insertion.

Using the system, depending on the selected type of implant (*plate*), the following may be performed:

- stabilization and immobilization of the cervical spine (*plates with four or more holes*)
- additional stabilization in combination with another cervical stabilization system (*plates with four or more holes*)
- protection against backing out of the intervertebral cervical cages from the intervertebral spaces after their implantation (*plates with two or more holes*).

1.1. MAIN FEATURES OF IMPLANTS

- low-profile, 1.9mm plates with open structure, pre-bent to fit cervical lordosis,
- hole plate design allows both rigid and angular positioning of locking screws,
- locking mechanism of elastic rings integrated with the plate holes prevents screw migration in the case of their loosening,
- set of self-tapping screws available in two diameters allows for single or bi-cortical fixation of the plate in the vertebral body,
- set of plates gives possibility of one-, two-, three- or four-level stabilization.



1.2. INDICATIONS

Plates with four or more holes may be used for:

a. Instabilities caused by trauma or associated with correction of cervical lordosis and kyphosis deformity.
b. Pseudoarthoses as a result of previously failed surgery.
c. Instabilities caused by major reconstructive surgery due to tumour.
d. Instabilities associated with single or multiple level corpectomy or discectomy.
e. Spinal canal stenoses and cervical myelopathy.

The two-hole plates are indicated for use with cervical intervertebral cages to protect them against backing out from intervertebral space.

Two-hole plates cannot be used to stabilize the cervical segment as a stand-alone implant!

2. IMPLANTS

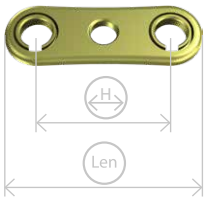
CHARSPINE system

2.1. CERVICAL LOCKING PLATE

Ster Non Ster

Two-hole plates

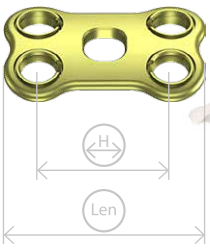
Len	H	Ti
23	14	3.3136.023
25	16	3.3136.025
27	18	3.3136.027
29	18	3.3136.029

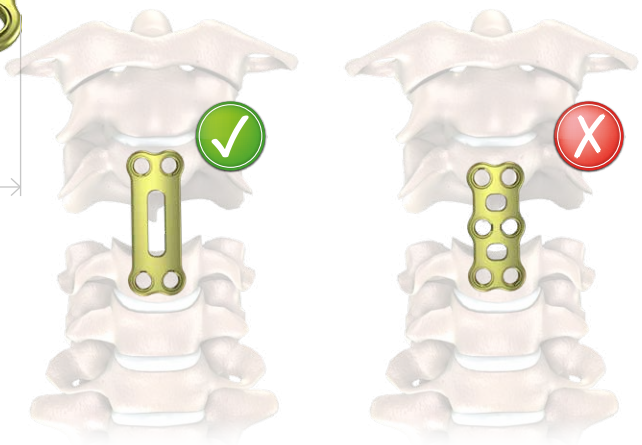


CAUTION:
Two-hole cervical locking plates are used with cervical intervertebral cages as a protection against their displacement from the intervertebral space.
Two-hole plates cannot be used to stabilize the cervical segment as a stand-alone implant!

Single-level plates

Len	H	Ti
23	14	3.3133.614
25	16	3.3133.616
28	18	3.3133.618
30	20	3.3133.620
32	22	3.3133.622
34	24	3.3133.624
36	26	3.3133.626
38	28	3.3133.628
45	35	3.3133.635

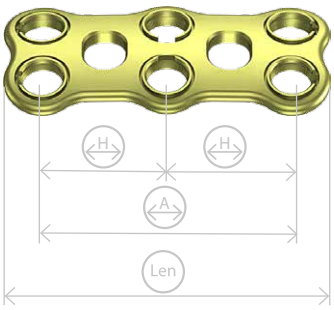




CAUTION:
For cervical corpectomy, only single-level plates should be used.
Multiple-level plates must not be used for this procedure.

Two-level plates

Len	H	A	Ti
37	14	28	3.3133.228
39	15	30	3.3133.230
41	16	32	3.3133.232
43	17	34	3.3133.234
46	18	36	3.3133.236



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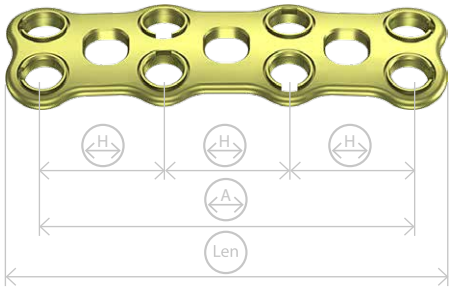
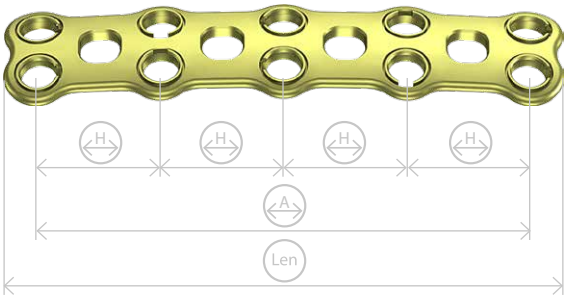
Three-level plates

Len	H	A	Ti
50	14	42	3.3133.342
53	15	45	3.3133.345
56	16	48	3.3133.348
59	17	51	3.3133.351
62	18	54	3.3133.354
65	19	57	3.3133.357



Four-level plates

Len	H	A	Ti
69	15	60	3.3133.460
73	16	64	3.3133.464
77	17	68	3.3133.468
81	18	72	3.3133.472
85	19	76	3.3133.476
89	20	80	3.3133.480



CHARSPINE system

2.2. CERVICAL LOCKING SCREW

	Ti	Len			VA	
	3.3201.012 3.3201.014 3.3201.016 3.3201.018	12 14 16 18	✓		✓	4.0
	3.3995.012 3.3995.014 3.3995.016 3.3995.018	12 14 16 18		✓	✓	4.0
	3.3202.012 3.3202.014 3.3202.016 3.3202.018	12 14 16 18	✓		✓	4.5
	3.3997.012 3.3997.014 3.3997.016 3.3997.018	12 14 16 18		✓	✓	4.5
	3.3998.012 3.3998.014 3.3998.016 3.3998.018	12 14 16 18	✓			4.0
	3.3994.012 3.3994.014 3.3994.016 3.3994.018	12 14 16 18		✓		4.0
	3.3999.012 3.3999.014 3.3999.016 3.3999.018	12 14 16 18	✓			4.5
	3.3996.012 3.3996.014 3.3996.016 3.3996.018	12 14 16 18		✓		4.5

40.4865.050
STAND FOR CERVICAL PLATES - SET

The stand provides space for the following implants:

Cervical locking screws Ø4	
Variable angle (VA)	
3.3201.012 or 3.3995.012	8 pcs
3.3201.012 or 3.3995.014	8 pcs
3.3201.012 or 3.3995.016.	8 pcs
3.3201.012 or 3.3995.018	8 pcs
Rigid	
3.3998.012 or 3.3994.012	8 pcs
3.3998.012 or 3.3994.014	8 pcs
3.3998.012 or 3.3994.016	8 pcs
3.3998.012 or 3.3994.018	8 pcs
Cervical locking screws Ø4.5	
Variable angle (VA)	
3.3202.012 or 3.3997.012	8 pcs
3.3202.012 or 3.3997.014	8 pcs
3.3202.012 or 3.3997.016	8 pcs
3.3202.012 or 3.3997.018	8 pcs
Rigid	
3.3999.012 or 3.3996.012	8 pcs
3.3999.012 or 3.3996.014	8 pcs
3.3999.012 or 3.3996.016	8 pcs
3.3999.012 or 3.3996.018	8 pcs
Cervical locking plate - 1 level	
3.3133.614	1 pcs
3.3133.616	1 pcs
3.3133.618	1 pcs
3.3133.620	1 pcs
3.3133.622	1 pcs
3.3133.624	1 pcs
3.3133.626	1 pcs
3.3133.628	1 pcs
3.3133.635	1 pcs
Cervical locking plate - 2 levels	
3.3133.228	1 pcs
3.3133.230	1 pcs
3.3133.232	1 pcs
3.3133.234	1 pcs
3.3133.236	1 pcs
Cervical locking plate - 3 levels	
3.3133.342	1 pcs
3.3133.345	1 pcs
3.3133.348	1 pcs
3.3133.351	1 pcs
3.3133.354	1 pcs
3.3133.357	1 pcs
Cervical locking plate - 4 levels	
3.3133.460	1 pcs
3.3133.464	1 pcs
3.3133.468	1 pcs
3.3133.472	1 pcs
3.3133.476	1 pcs
3.3133.480	1 pcs

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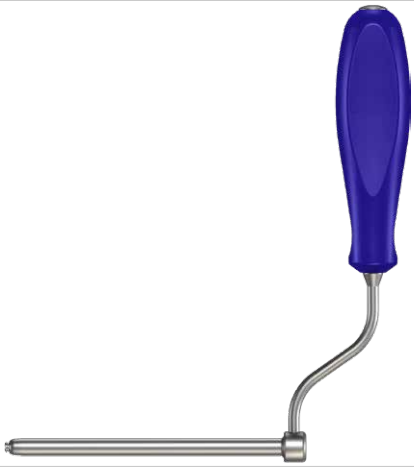
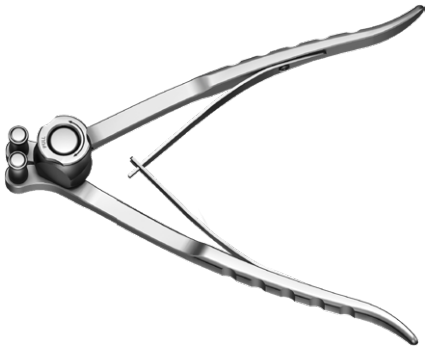
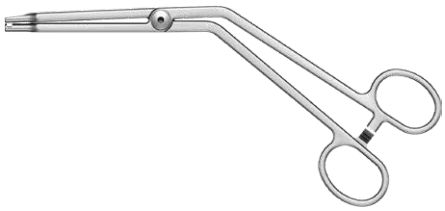
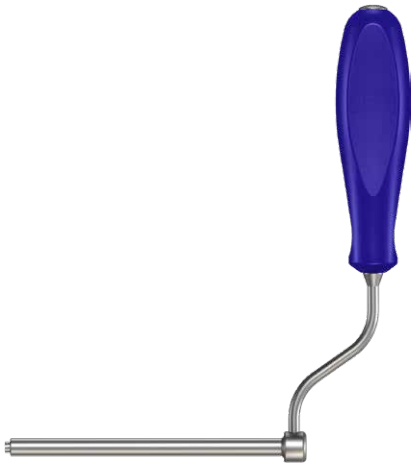
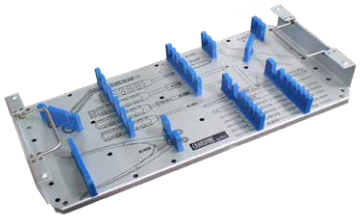
3. INSTRUMENT SET

CHARSPINE system

40.4820.700	Name	Catalogue no.	Pcs
	Trocar C	40.4821.100	1
	Drill guide C - multiangular	40.4825.100	1
	Positioning screw C	40.4826.225	2
	Plates bender	40.4830.000	1
	Drill with limiter C 2.2/12	40.4831.512	1
	Drill with limiter C 2.2/14	40.4831.514	1
	Drill with limiter C 2.2/16	40.4831.516	1
	Drill with limiter C 2.2/18	40.4831.518	1
	Handle ratchet device	40.6654.001	1
	Screwdriver for cervical screws - solid	40.5286.500	1
	Plate holder	40.4832.100	1
	Hole depth measure C	40.4833.100	1

CHARSPINE system

40.4820.700	Name	Catalogue no.	Pcs
	Plate size measure	40.4834.100	1
	Drill guide C - rigid	40.4836.100	1
	Screwdriver for locking cervical screws	40.4828.100	1
	Perforated aluminum lid 1/1 595x275x15mm Gray	12.0750.200	1
	Stand for instrument set for cervical locking plates	40.4838.700	1
	Container with solid bottom 1/1 595x275x86mm	12.0750.100	1

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4. SURGICAL APPROACH

Anterior approach to the cervical spine

For plate osteosynthesis of cervical spine, the anterior approach allowing visibility of the vertebral bodies from C3 to Th1 is used.

Patient positioning

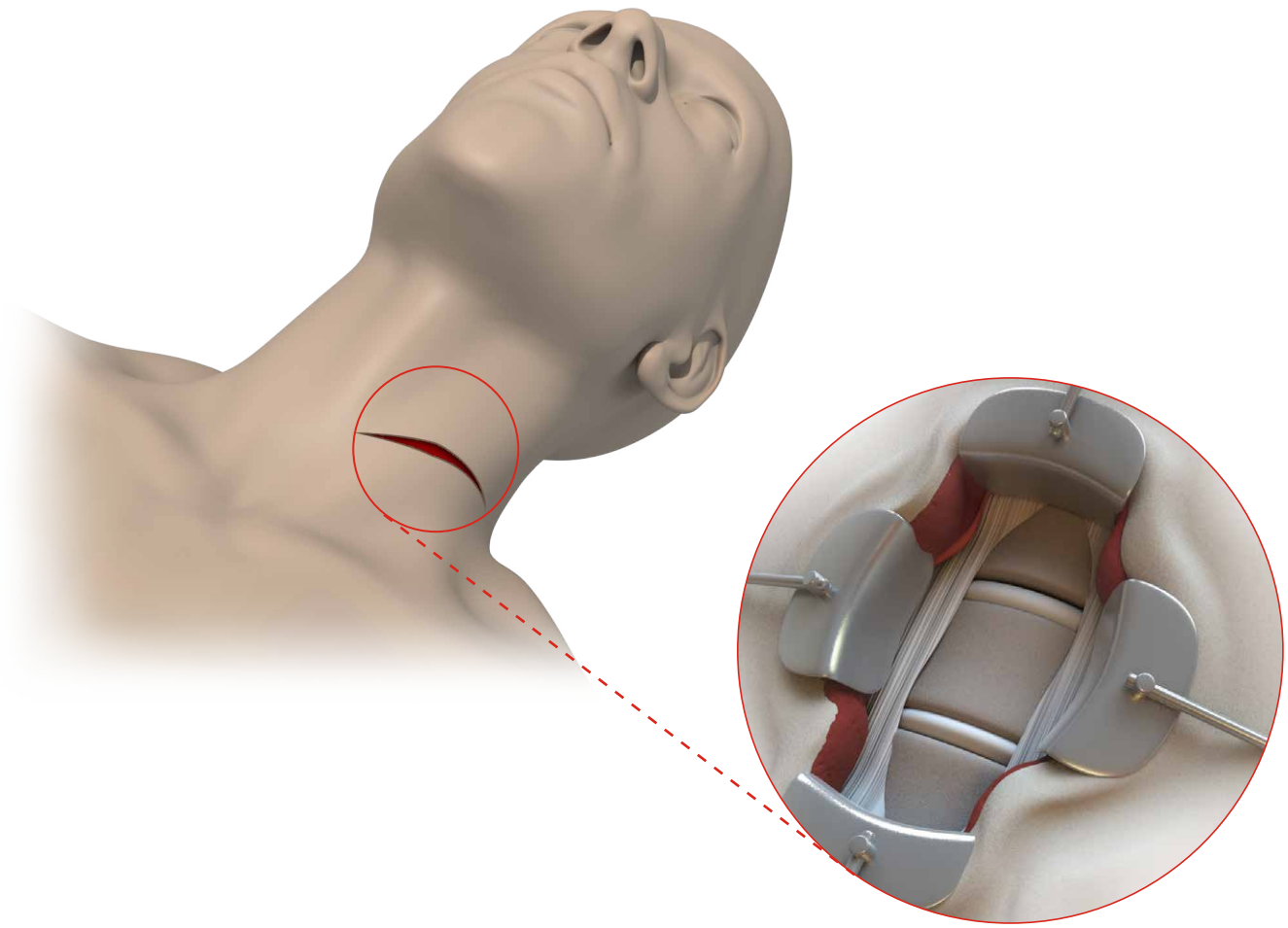
Patient is placed supine, with a small pillow between the shoulders to secure the neck in an extended position. Patient's head is turned in the opposite direction to the planned skin incision. If necessary, skeletal traction or loop may be used directly with the skull. This can be useful at a later stage of the operation, when there is a need for some distraction of cervical spine.

It is advisable to tilt the operating table at about 30° (*Trendelenburg position*) to prevent bleeding and to ensure adequate access to the neck. Confirm intraoperatively the spine level planned for treatment using X-Ray vision. For cosmetic effects, transverse incision is recommended (*the postoperative scar is covered with the natural folds of skin*). Left-sided access is preferred due to the lower risk of accidental damage to the recurrent laryngeal nerve. The incision should be preformed obliquely from the midline to the posterior edge of sternocleidomastoid muscle.

After reaching the front surface of the vertebrae, the automatic retractor may be applied to retract muscles. Care must be taken to not damage the oesophagus or neurovascular bundle of neck. Access widening may be performed with appropriate protection of recurrent laryngeal nerve, trachea and esophagus.

The desired treatment level is identified and confirmed with a lateral radiograph. Afterwards, discectomy and resection of osteophytes can be performed.

Removal of the osteophytes is essential for proper placement of a locking plate.



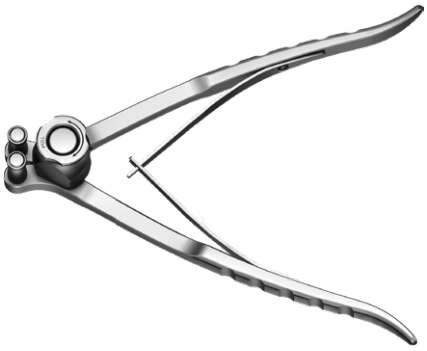
5. SURGICAL TECHNIQUE

5.1. PLATE SELECTION

1 Before spinal decompression and plate implantation, use the plate size measure **[40.4834.100]** to define the proper size of the intervertebral graft or vertebral prosthesis. Implant the device and then use the same measure to choose adequate locking plate.

40.4834.100

2 Make sure that factory-made curvature of the selected plate fits anatomical curvature of the spine. If needed, the plate curvature may be modified using the plates bender **[40.4830.000]**.



40.4830.000

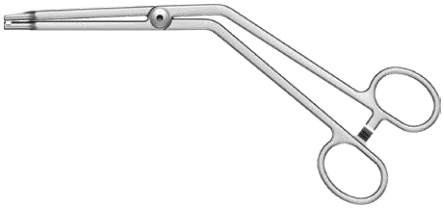
Lordotic curvature increase

Lordotic curvature decrease

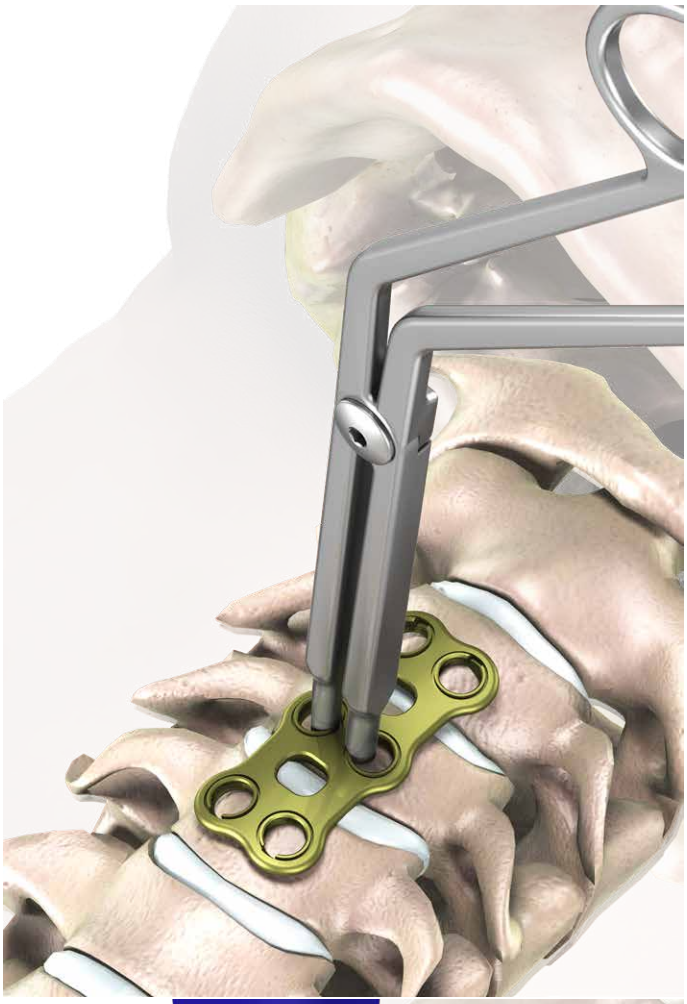
- The plate shall be bent between the holes designed for screws insertion.
- Multiple bending can cause mechanical weakening or/and the implant damage!

5.2. PLATE IMPLANTATION - TEMPORARY LOCKING USING POSITIONING SCREWS

3 Use plate holder **[40.4832.100]** to position the plate on the surface of vertebral bodies.



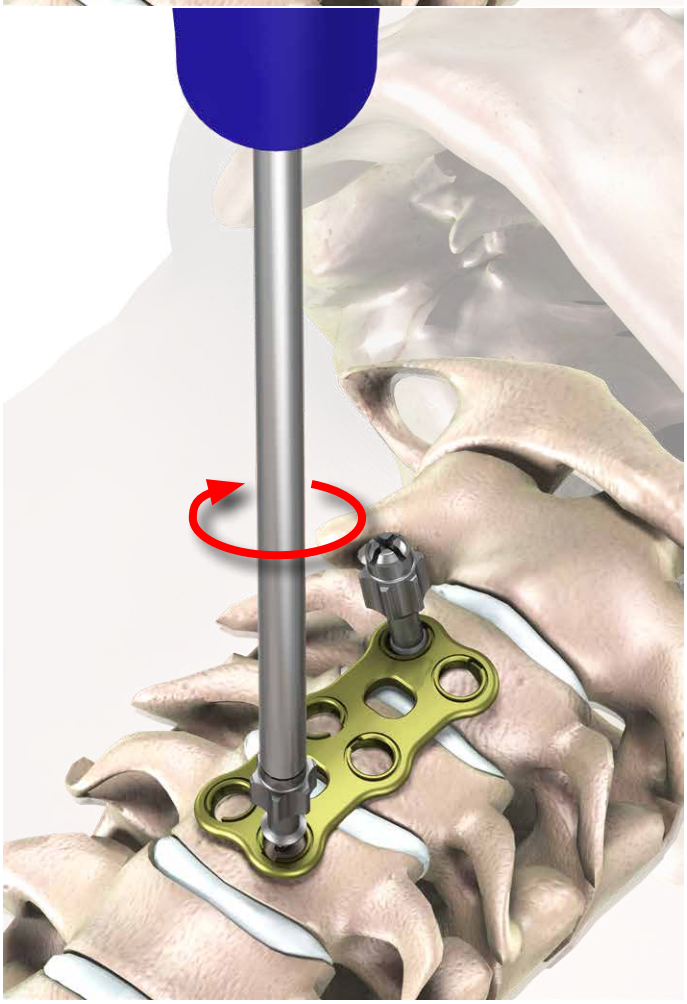
40.4832.100



4 To maintain the desired position of the plate, attach it to the vertebral bodies using one or two positioning screws **[40.4826.225]**. Insert positioning screws using screwdriver for cervical screws - solid **[40.5286.500]** (*blue handle*) under the image intensifier control.

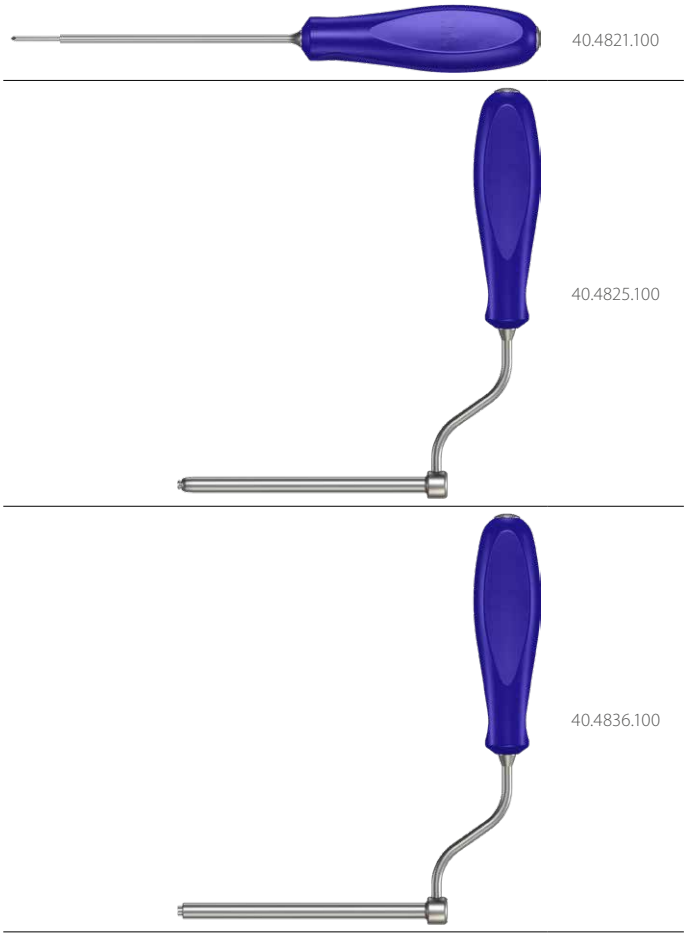
40.5286.500

The trajectory of the positioning screw forces a subsequent trajectory of the locking screw.

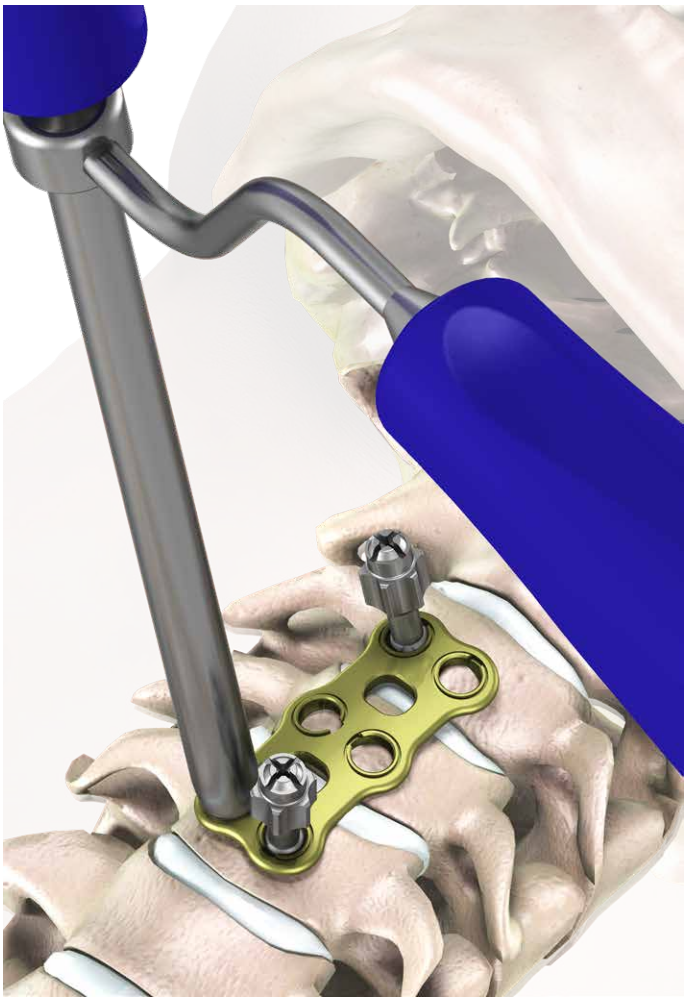


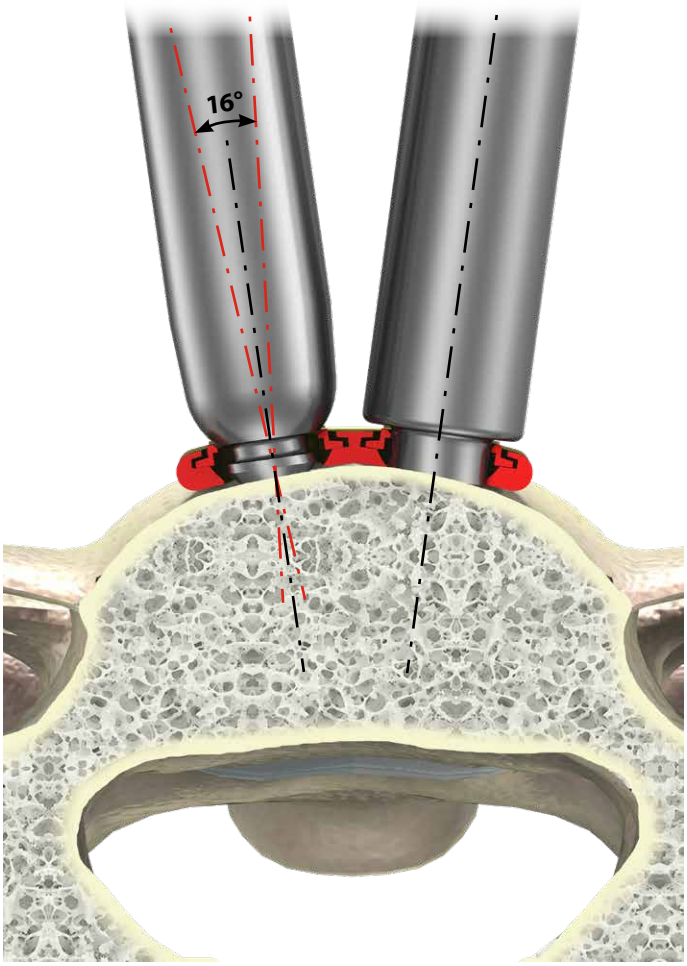
5.3. CORTICAL PENETRATIONS

5 Cortical penetration may be performed using trocar C **[40.4821.100]** which is inserted through the drill guide C **[40.4825.100]** or **[40.4836.100]**. Insert the rounded tip of the drill guide C into the hole of the plate. The drill guide C - rigid **[40.4836.100]** shall be positioned in the axis of the plate hole, while drill guide C - multiangular **[40.4825.100]** is to be positioned angularly, in a desired position. Cortical penetration is obtained by pushing the trocar C until stop, for the depth of about 5 mm.



The drill guide C - multiangular **[40.4825.100]** is intended for use with variable angle screws, while drill guide C - rigid **[40.4836.100]** for use with fixed angle screws.



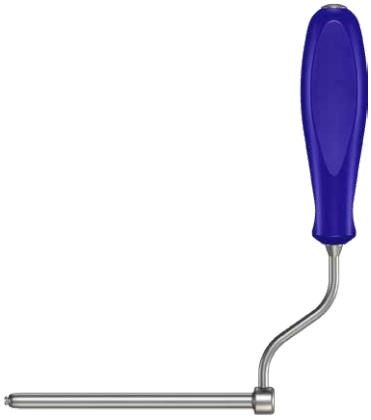


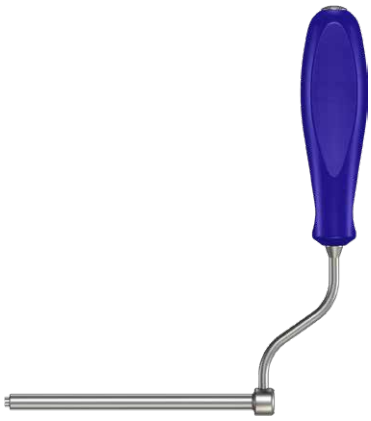
5.4. HOLES DRILLING

6 Should holes drilling be necessary, use one of four drills with limiter C **[40.4831.5xx]** available in the set. The chosen drill should be used with handle ratchet device **[40.6654.001]**.
Based on X-Ray images, the appropriate drill length shall be chosen (*the drill sizes correspond to the lengths of locking screws*). Then insert the tip of drill guide C **[40.4825.100]** or **[40.4836.100]** into a hole for the locking screw and then the chosen drill. The drilling process shall be performed under X-Ray control until reaching the limiter of the drill.
Verify the correctness of the hole drilled under X-Ray control.

40.4831.5xx


40.6654.001

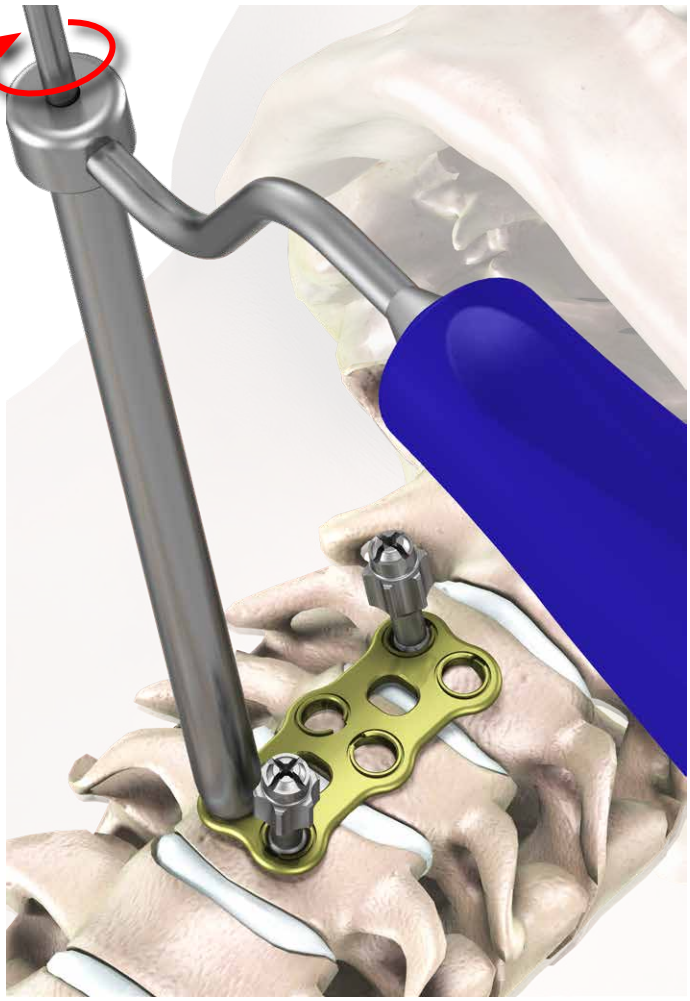

40.4825.100

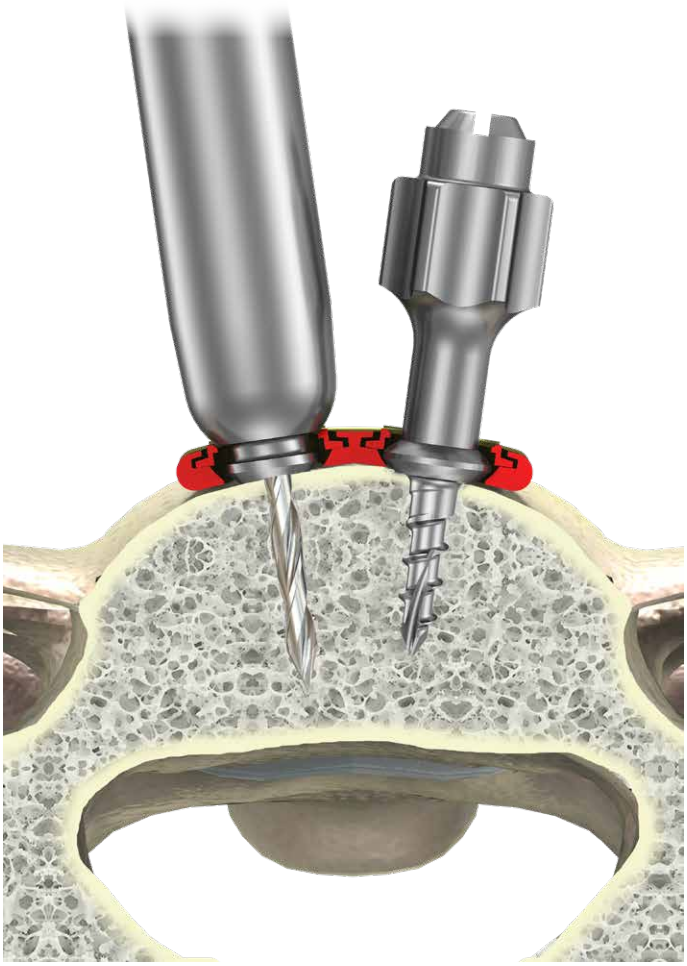

40.4836.100

The drilling process shall be controlled with image intensifier.

The trocar C **[40.4821.100]** and drills **[40.4831.5xx]** shall be used only with drill guides C **[40.4825.100]** or **[40.4836.100]**.


40.4821.100

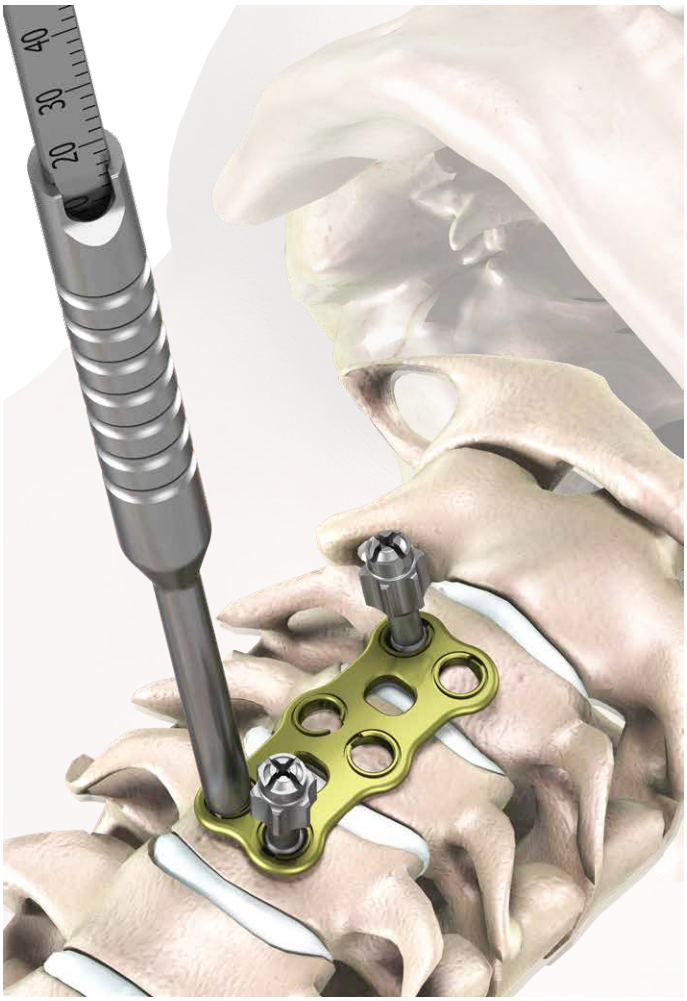




5.5. SCREWS SELECTION AND IMPLANTATION

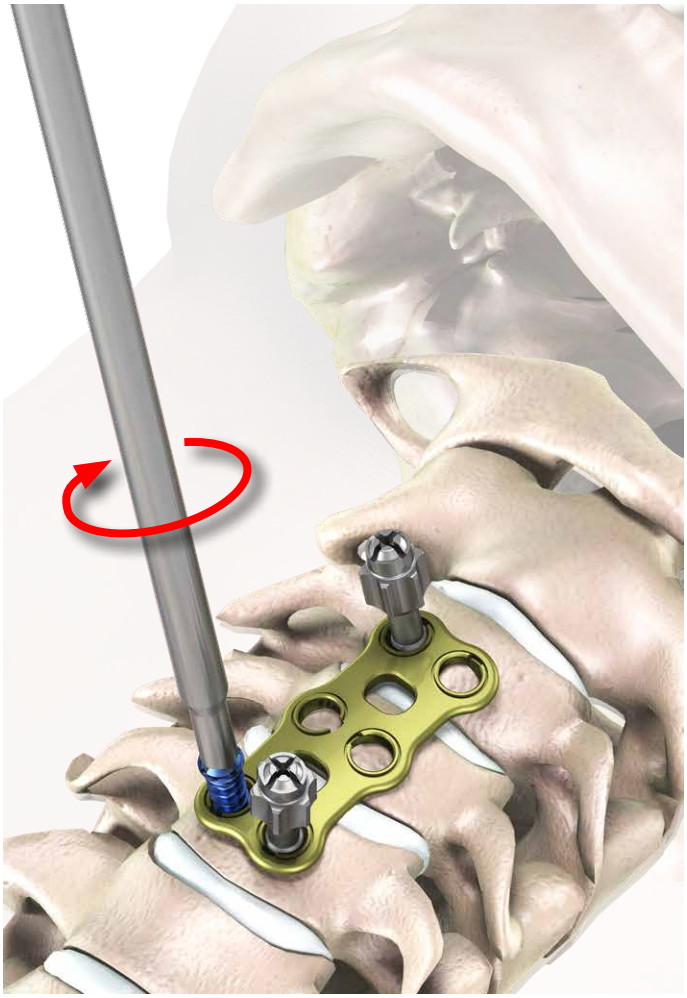
7 If needed, the drilled hole can be measured using the hole depth measure C **[40.4833.100]**. The tip of the measure shall be inserted into the hole until stop. Read the length of the locking screws on the measure scale. The value indicated on the device corresponds to the length of the locking screw.

40.4833.100

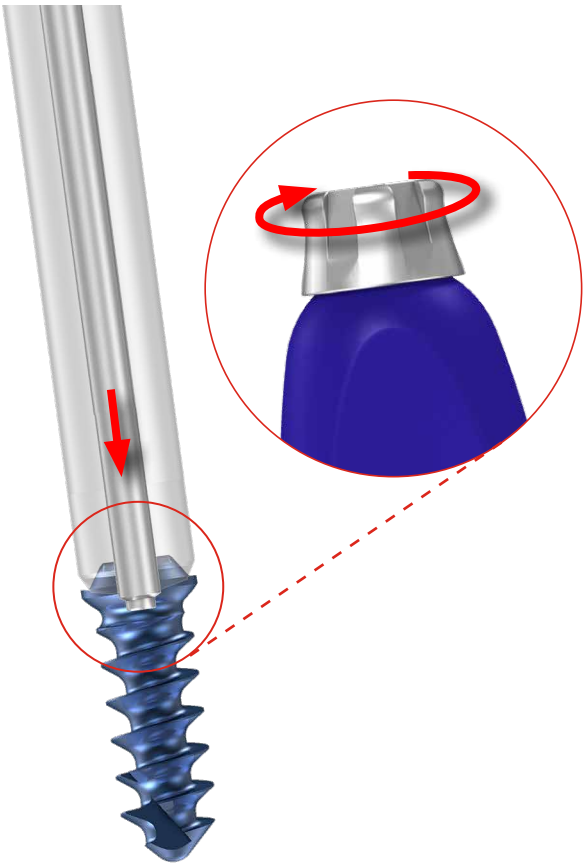


8 The tip of the screwdriver for cervical screws - solid **[40.5286.500]** (*blue handle*) is inserted into the head of the locking screw that subsequently is secured with the locking pin and pin knob. The screw is inserted into the plate hole and tightened until 'click' sound is heard (*the safety mechanism integrated with the plate has been activated*). Afterwards, disconnect the screwdriver from the implanted screw with counterclockwise rotation of the pin knob.

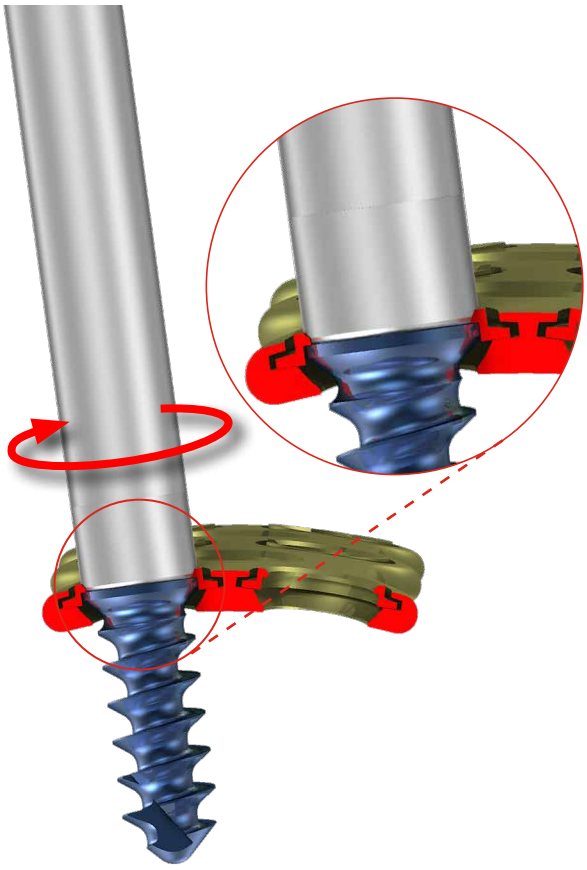
40.5286.500



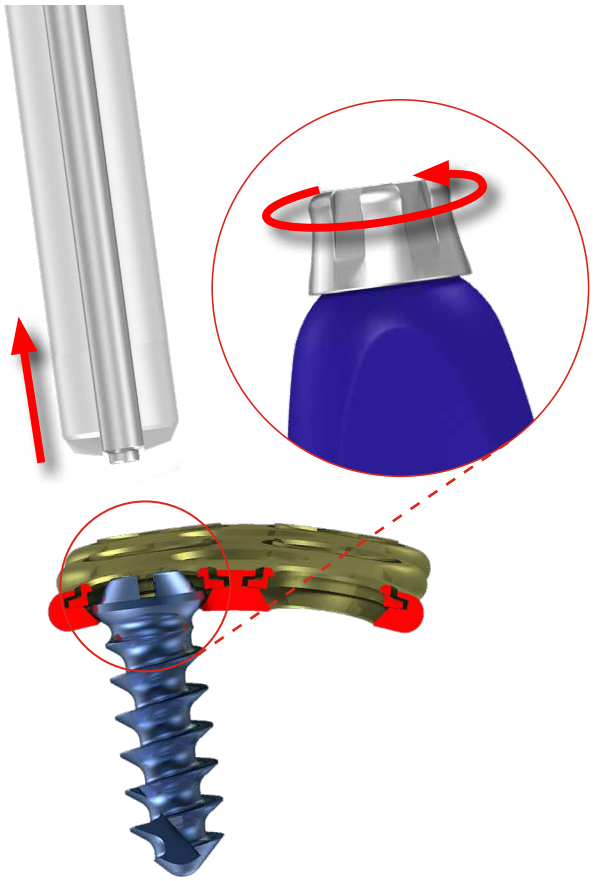
• Connection of the screw head and screwdriver tip



• Tightening the pin knob and securing the screw on the tip

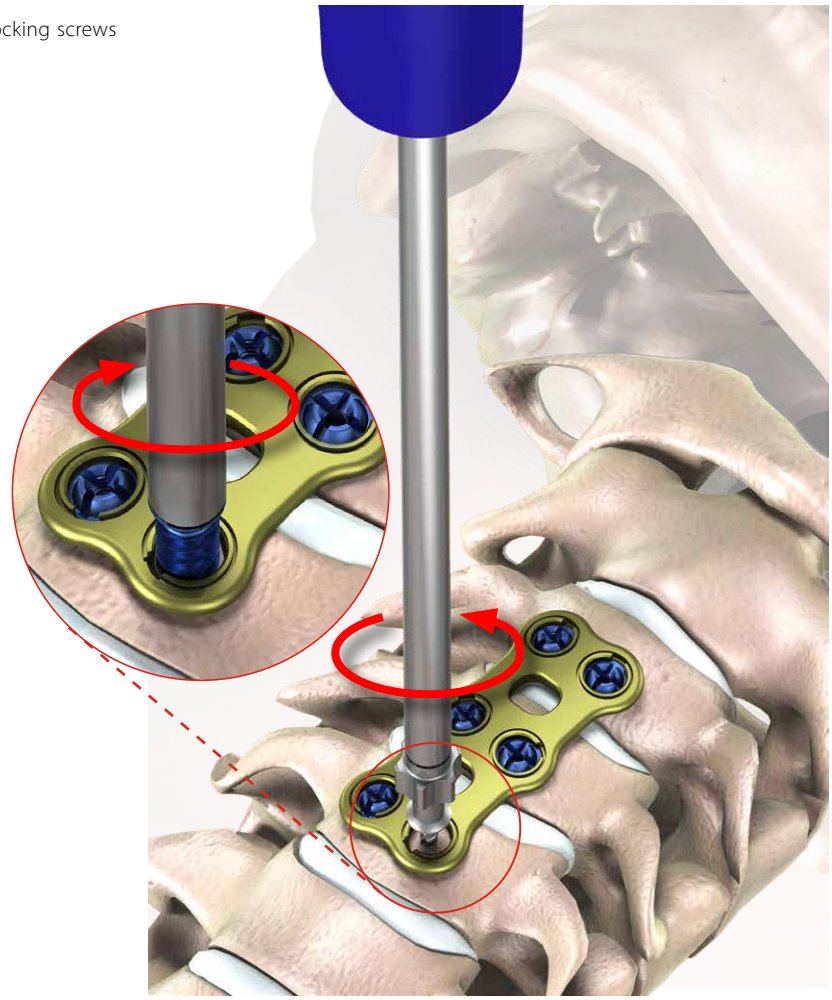


• Insertion of the screw into the plate hole and its locking by the locking ring



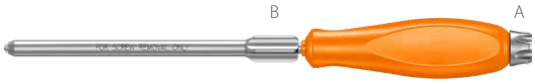
• Disengagement of the pin and screwdriver removal

9 Having removed positioning screws, insert the other locking screws and fix the plate to the bone.

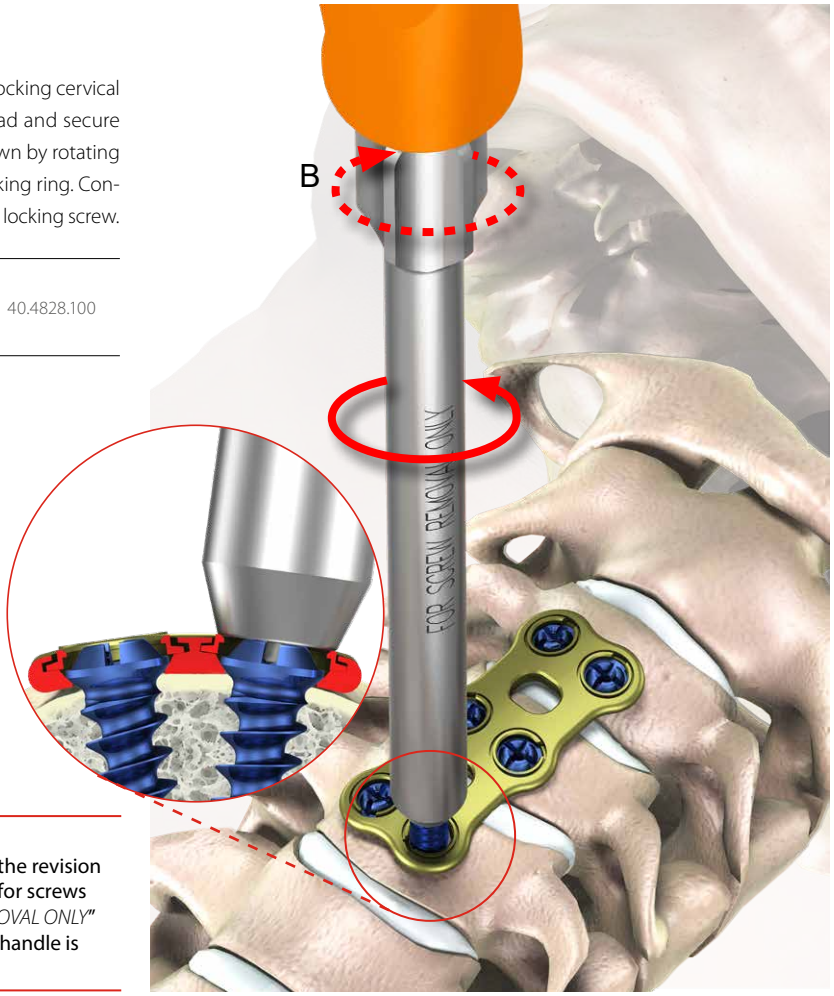


5.6. SCREWS REMOVAL

10 If plate removal is needed, insert the tip of screwdriver for locking cervical screws **[40.4828.100]** (*orange handle*) into the screw head and secure it by turning the knob A. Then slide the sleeve B of screwdriver down by rotating it clockwise until the conical end of the sleeve expands elastic locking ring. Continue sliding until the head of sleeve rests on the screw. Remove the locking screw.



40.4828.100



CAUTION:

- The screwdriver **[40.4828.100]** is used only for the revision removal of locking screws. It must not be used for screws implantation. To avoid misuse, „*FOR SCREW REMOVAL ONLY*" has been marked on its tip and sleeve, and the handle is marked orange.

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