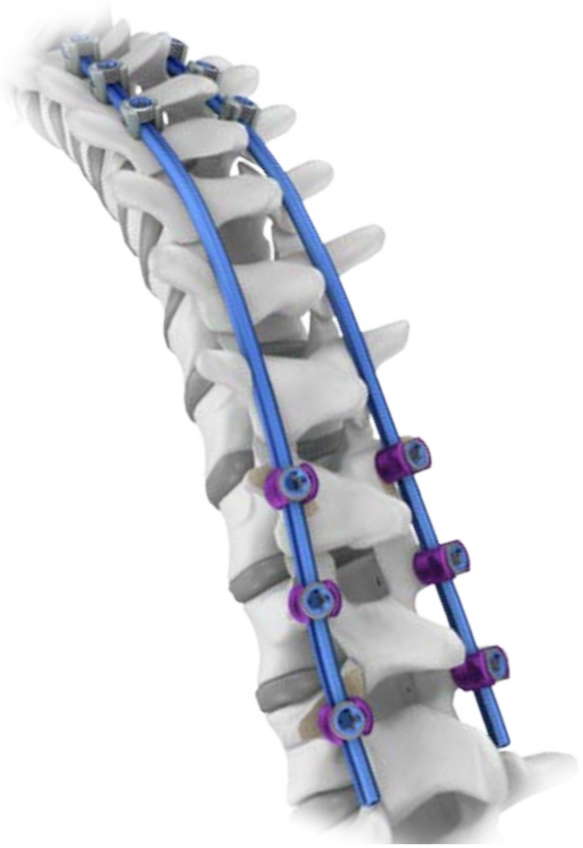
ST/63A

CHARSPINE system 2

SPINE STABILIZATION

- *IMPLANTS*
- *INSTRUMENT SET 40.8060.000*
- *INSTRUMENT SET 40.8061.000*
- *SURGICAL TECHNIQUE*



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Date: 2021.04.12 17:43:58 EEST
Reason: MoldSign Signature
Location: Moldova

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SYMBOLS DESCRIPTIONS	
	Caution - pay attention to the particular proceeding.
	Perform the activity with X-Ray control.
	Information about the next stages of the proceedings
	Proceed to the next stage.
	Return to the specified stage and repeat the activity.

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Document No ST/63A
Date of issue 01.06.2015
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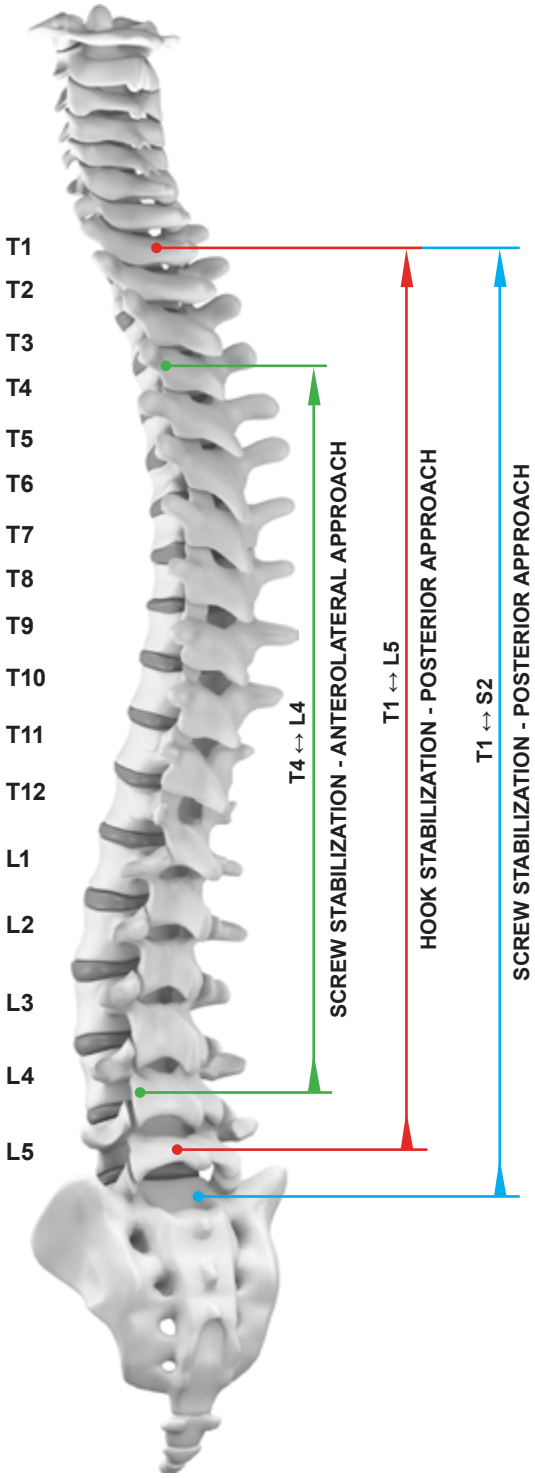
I. INTRODUCTION

CHARSPINE2 Thoracolumbar Spinal Stabilization System is the set of universal spinal fixation implants for thoracolumbar and lumbar spine treatment in skeletally mature patients:

- via posterior approach
  screw fixation from T1 *(T3)* to S2
  hook fixation from T1 *(T3)* to L5
- via anterolateral approach
  screw fixation from T4 *(T6)* to L4 *(L3)*

CHARSPINE2 system consists of:
- implants *(screws, hooks, connectors, locking elements, staples, and others)*,
- instruments for implants insertion,
- instructions for use and surgical technique.



INDICATIONS

CHARSPINE2 implants allow for treatment intended for spinal physiological curvature reconstruction by means of appropriate vertebrae reposition.
Indications for use:
- degenerative disc disease,
- spondylolistheses,
- fractures and instabilities,
- deformities *(e.g. scolioses or kyphoses)*,
- tumours,
- stenoses,
- pseudoarthroses,
- nonunion following the previous procedures.

CONTRAINDICATIONS

Contraindications may be relative and absolute. One should thoroughly consider the selection of an appropriate implant on the basis of comprehensive assessment of patient's health condition. Some conditions such as spinal infection, morbid obesity, mental disease, alcohol or drug addiction, pregnancy, oversensitivity to metals/foreign bodies, insufficient tissue coverage or open wound in the operative site may reduce the chances of surgery or make the success impossible.

A detailed list of contraindications is presented in instructions for use *(IFU)* intended for this device.

WARNINGS

Safety and effectiveness of spinal systems based upon pedicle screw fixation have been established only for pathological spinal conditions caused by significant mechanical instability or deformations requiring surgical fixation.
Safety and effectiveness of these systems for any other conditions are unknown.

It is not always possible to achieve positive results in each and every patient. This especially applies to procedures in which other conditions related to patient's state may make it impossible to achieve the positive results.

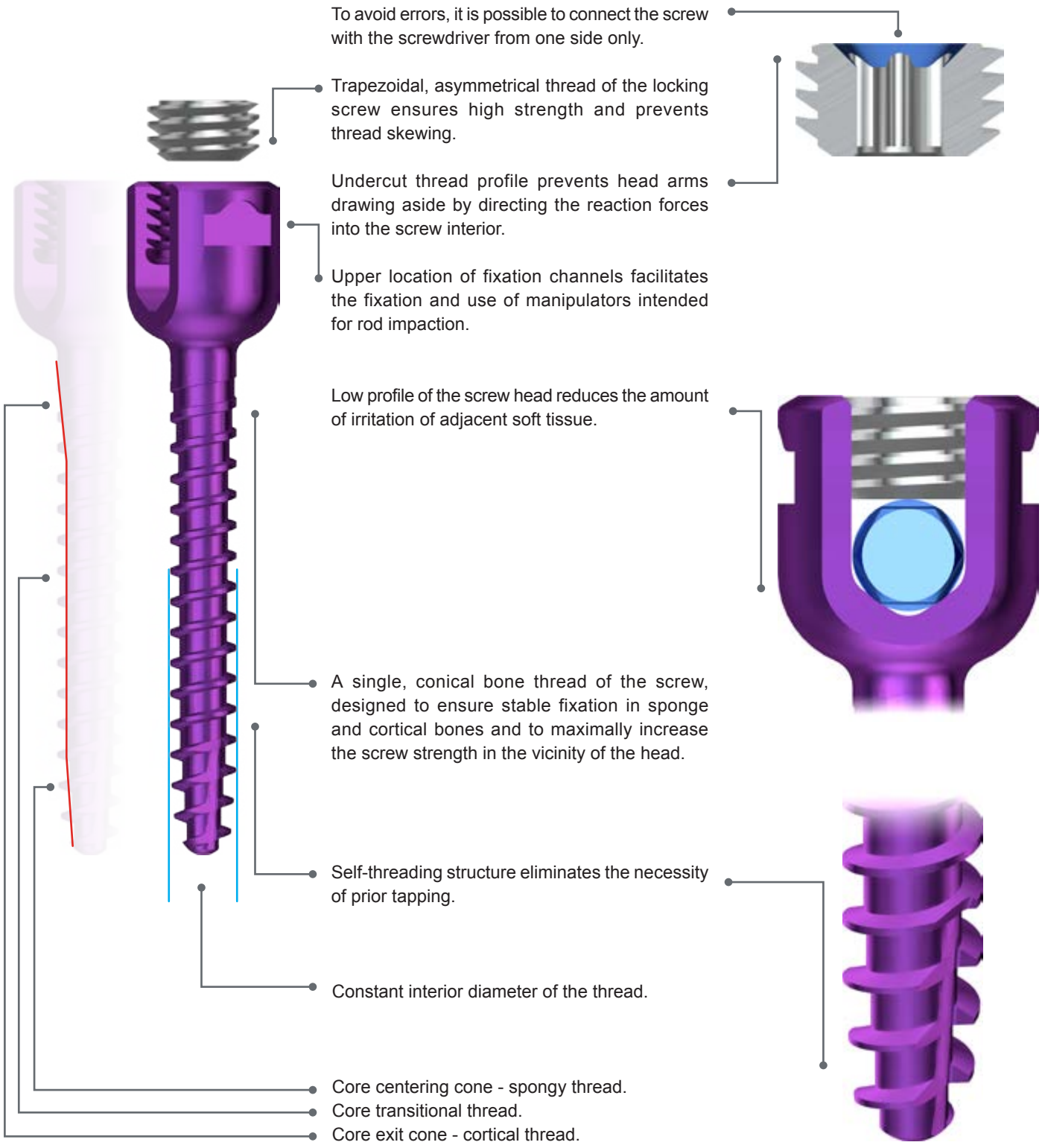
The final result is greatly influenced by appropriate patient selection and patient's observance of postoperative recommendations. It is proved that smoking hampers the bone union. Patients should be informed about this correlation and warned about the consequences.

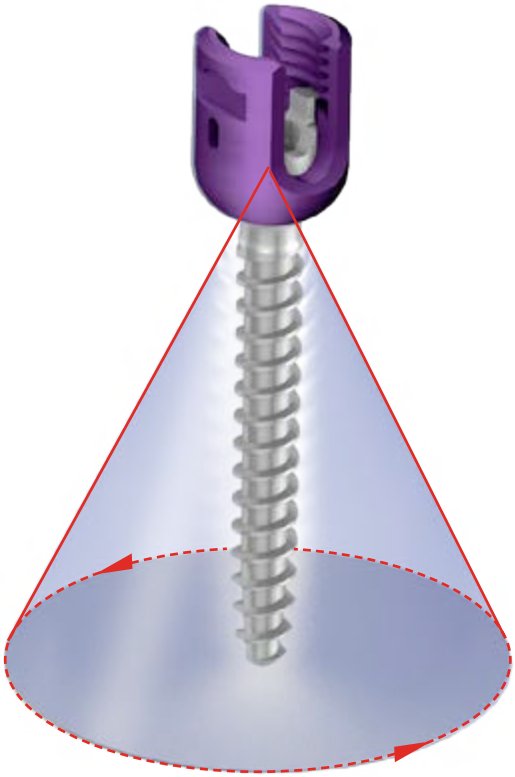
A detailed list of warnings, precautions and postoperative recommendations is presented in instructions for use *(IFU)* intended for this device.

Implants from the ChM CHARSPINE2 spine stabilization system are designed and tested to be used only with the appropriate ChM instrument set.
This surgical technique is intended as a guide only. As with any surgical procedure, the surgeon should be thoroughly trained before the procedure and must take into consideration the particular needs of each patient.

MAIN FEATURES AND BENEFITS

Solutions used in implants and instrument set to posterior and anterolateral approach.
The presented range of implants is made of titanium, titanium alloys and cobalt alloy in accordance with ISO 5832 standard. Compliance with the requirements of Quality Management Systems ISO 9001, EN ISO 13485 and the requirements of Directive 93/42/EEC concerning medical devices guarantee high quality of the offered implants.

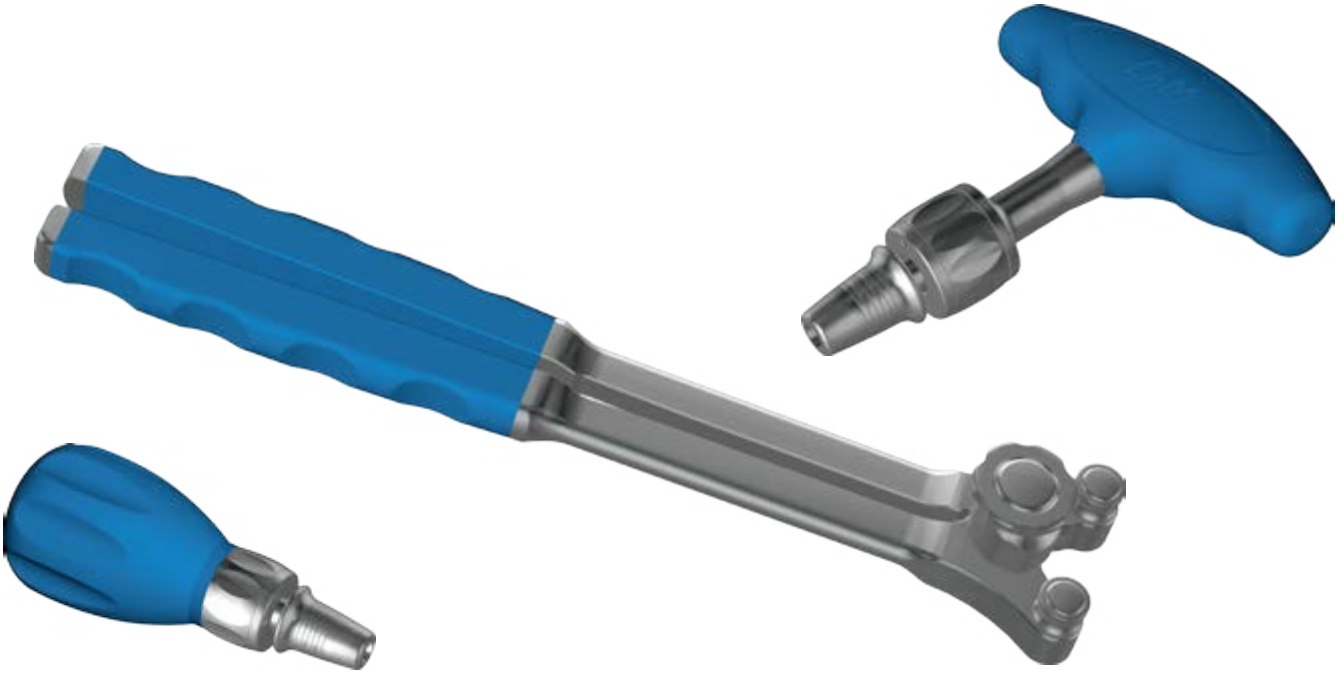




Polyaxial screws allow for stable angular fixation of the screw head within the range of 45°.

A new generation of surgical instruments was prepared for CHARSPINE2 system, aiming at maximization of their ergonomics, functionality and effectiveness.

The instruments have original **ChM** branded silicon handles that improve the ergonomics and comfort of a grip.



II. IMPLANTS

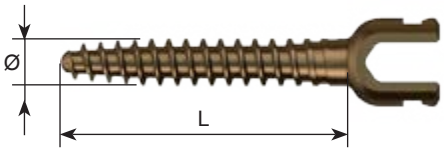
CHARSPINE system 2

TITANIUM ALLOY Ti

CHARSPINE2 Monoaxial screw

Locking screw

Catalogue no.
3.6160.000



Ø4	Ø4.5	Ø5	Ø5.5	Ø6	Ø6.5	Ø7.5	Ø8.5	Ø9.5

Colors

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	Catalogue no.								
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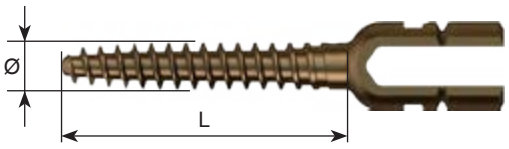
30	3.6150.130	3.6151.130	3.6152.130	3.6153.130	3.6154.130	3.6155.130	3.6156.130	3.6157.130	3.6158.130
35	3.6150.135	3.6151.135	3.6152.135	3.6153.135	3.6154.135	3.6155.135	3.6156.135	3.6157.135	3.6158.135
40	3.6150.140	3.6151.140	3.6152.140	3.6153.140	3.6154.140	3.6155.140	3.6156.140	3.6157.140	3.6158.140
45	3.6150.145	3.6151.145	3.6152.145	3.6153.145	3.6154.145	3.6155.145	3.6156.145	3.6157.145	3.6158.145
50	—	—	3.6152.150	3.6153.150	3.6154.150	3.6155.150	3.6156.150	3.6157.150	3.6158.150
55	—	—	—	3.6153.155	3.6154.155	3.6155.155	3.6156.155	3.6157.155	3.6158.155
60	—	—	—	—	3.6154.160	3.6155.160	3.6156.160	3.6157.160	3.6158.160
65	—	—	—	—	3.6154.165	3.6155.165	3.6156.165	3.6157.165	3.6158.165
70	—	—	—	—	—	—	3.6156.170	3.6157.170	3.6158.170
75	—	—	—	—	—	—	3.6156.175	3.6157.175	3.6158.175
80	—	—	—	—	—	—	3.6156.180	3.6157.180	3.6158.180
85	—	—	—	—	—	—	3.6156.185	3.6157.185	3.6158.185
90	—	—	—	—	—	—	3.6156.190	3.6157.190	3.6158.190

CHARSPINE2 Monoaxial reduction screw

Locking screw

Catalogue no.
3.6160.000



L [mm]	Ø4	Ø4.5	Ø5	Ø5.5	Ø6	Ø6.5	Ø7.5	Ø8.5	Ø9.5
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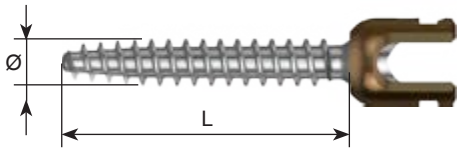
35	3.6161.135	3.6162.135	3.6163.135	3.6164.135	3.6165.135	3.6166.135	3.6167.135	3.6168.135	3.6169.135
40	3.6161.140	3.6162.140	3.6163.140	3.6164.140	3.6165.140	3.6166.140	3.6167.140	3.6168.140	3.6169.140
45	3.6161.145	3.6162.145	3.6163.145	3.6164.145	3.6165.145	3.6166.145	3.6167.145	3.6168.145	3.6169.145
50	—	—	3.6163.150	3.6164.150	3.6165.150	3.6166.150	3.6167.150	3.6168.150	3.6169.150
55	—	—	—	3.6164.155	3.6165.155	3.6166.155	3.6167.155	3.6168.155	3.6169.155
60	—	—	—	—	3.6165.160	3.6166.160	3.6167.160	3.6168.160	3.6169.160
65	—	—	—	—	3.6165.165	3.6166.165	3.6167.165	3.6168.165	3.6169.165
70	—	—	—	—	—	—	3.6167.170	3.6168.170	3.6169.170
75	—	—	—	—	—	—	3.6167.175	3.6168.175	3.6169.175
80	—	—	—	—	—	—	3.6167.180	3.6168.180	3.6169.180
85	—	—	—	—	—	—	3.6167.185	3.6168.185	3.6169.185
90	—	—	—	—	—	—	3.6167.190	3.6168.190	3.6169.190

ChM sp. z o.o., Lewickie 3b, 16-061 Juchnowiec Kościelny, POLAND, tel. + 48 85 713 13 20, fax + 48 85 713 13 19, chm@chm.eu, www.chm.eu

CHARSPINE2 Polyaxial screw

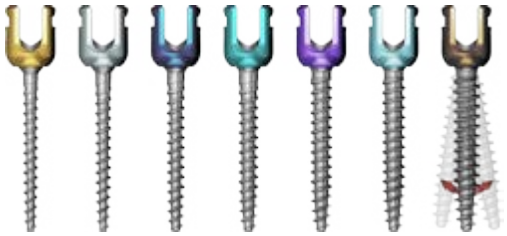
Locking screw

Catalogue no.
3.6160.000



Ø4	Ø4.5	Ø5	Ø5.5	Ø6	Ø6.5	Ø7.5

Colors



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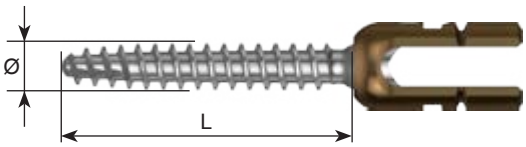
40	3.6170.040	3.6171.040	3.6172.040	3.6173.040	3.6174.040	3.6175.040	3.6176.040
45	3.6170.045	3.6171.045	3.6172.045	3.6173.045	3.6174.045	3.6175.045	3.6176.045
50	—	—	3.6172.050	3.6173.050	3.6174.050	3.6175.050	3.6176.050
55	—	—	—	3.6173.055	3.6174.055	3.6175.055	3.6176.055
60	—	—	—	—	3.6174.060	3.6175.060	3.6176.060
65	—	—	—	—	3.6174.065	3.6175.065	3.6176.065
70	—	—	—	—	—	—	3.6176.070
75	—	—	—	—	—	—	3.6176.075
80	—	—	—	—	—	—	3.6176.080
85	—	—	—	—	—	—	3.6176.085
90	—	—	—	—	—	—	3.6176.090

CHARSPINE2 Polyaxial reduction screw

Locking screw

Catalogue no.
3.6160.000



L [mm]	Ø4	Ø4.5	Ø5	Ø5.5	Ø6	Ø6.5	Ø7.5
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40	3.6177.040	3.6178.040	3.6179.040	3.6180.040	3.6181.040	3.6182.040	3.6183.040
45	3.6177.045	3.6178.045	3.6179.045	3.6180.045	3.6181.045	3.6182.045	3.6183.045
50	—	—	3.6179.050	3.6180.050	3.6181.050	3.6182.050	3.6183.050
55	—	—	—	3.6180.055	3.6181.055	3.6182.055	3.6183.055
60	—	—	—	—	3.6181.060	3.6182.060	3.6183.060
65	—	—	—	—	3.6181.065	3.6182.065	3.6183.065
70	—	—	—	—	—	—	3.6183.070
75	—	—	—	—	—	—	3.6183.075
80	—	—	—	—	—	—	3.6183.080
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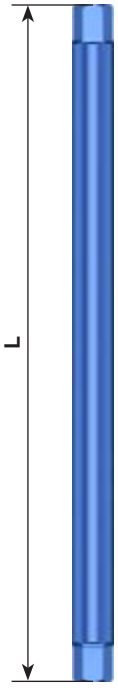
90	—	—	—	—	—	—	3.6183.090

Rod Ø6

TITANIUM ALLOY Ti



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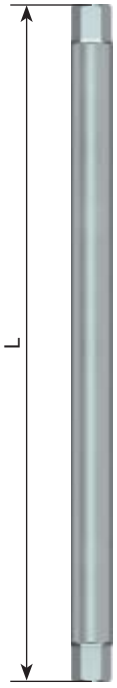
220	3.3246.220
260	3.3246.260
300	3.3246.300
360	3.3246.360
400	3.3246.400
460	3.3246.460
500	3.3246.500

Rod Ø6

COBALT ALLOY Co

Extra high rigidity



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70	4.3980.070
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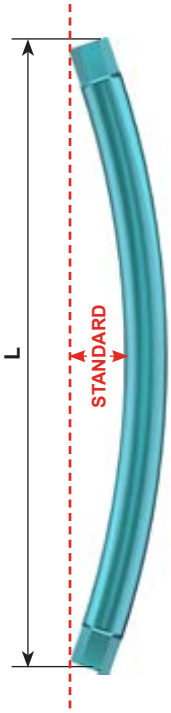
90	4.3980.090
100	4.3980.100
120	4.3980.120
160	4.3980.160
200	4.3980.200
220	4.3980.220
260	4.3980.260
300	4.3980.300
360	4.3980.360
400	4.3980.400
460	4.3980.460
500	4.3980.500

Curved rod Ø6

TITANIUM ALLOY Ti



L [mm]	Ø6
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65	3.6280.065
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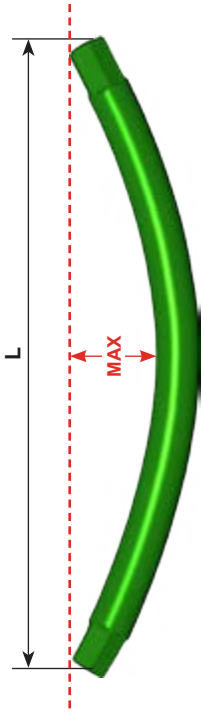
75	3.6280.075
80	3.6280.080
85	3.6280.085

Curved rod Ø6

TITANIUM ALLOY Ti



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65	3.6295.065
70	3.6295.070
75	3.6295.075
80	3.6295.080
85	3.6295.085

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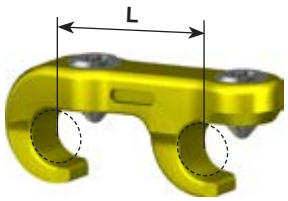
Crosswise connector solid *(set)*



L [mm]	Catalogue no.
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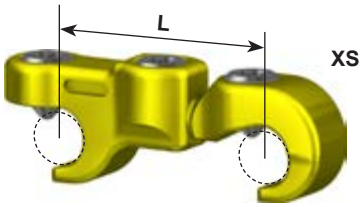
16	3.6290.016
17	3.6290.017
18	3.6290.018
19	3.6290.019
20	3.6290.020
21	3.6290.021
22	3.6290.022

L [mm]	Catalogue no.
23	3.6290.023
24	3.6290.024
25	3.6290.025
26	3.6290.026
27	3.6290.027
28	3.6290.028
29	3.6290.029
30	3.6290.030

Crosswise connector regulated



XS

	L [mm]	Catalogue no.
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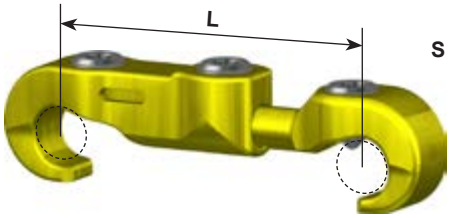
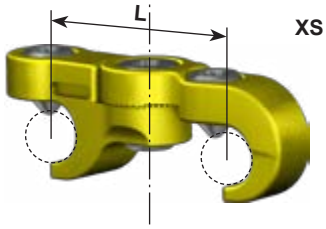


S - XL

	L [mm]	Catalogue no.
S	30.5-33	3.3979.030
M	33-38.5	3.3979.033
L	38.5-49	3.3979.038
XL	49-71	3.3979.049



XS

	L [mm]	Catalogue no.
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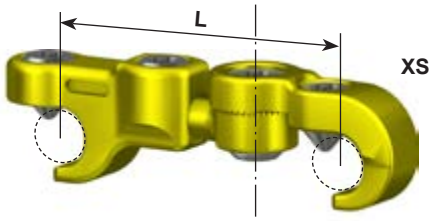
XS	28	3.6296.028
XS	30	3.6296.030
XS	32	3.6296.032
XS	34	3.6296.034



XS

	L [mm]	Catalogue no.
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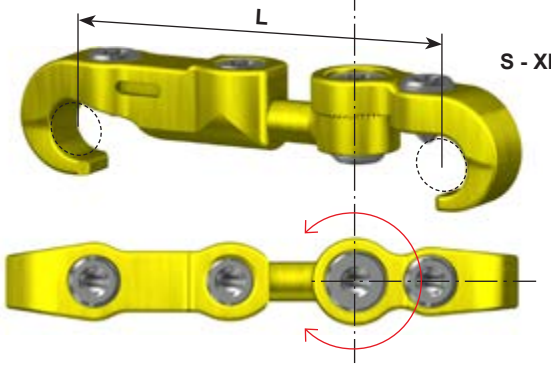

S - XL

	L [mm]	Catalogue no.
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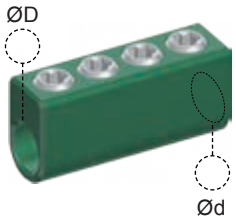
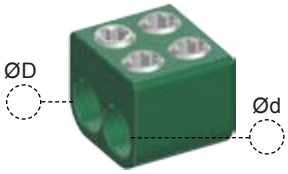
M	40-45.5	3.3972.040
L	45.5-56.5	3.3972.045
XL	56.5-78	3.3972.056
XXL	78-99	3.3972.078

Axial connector *(set)*



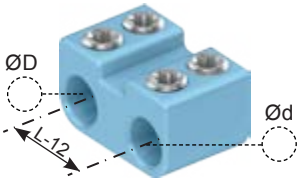
Ød [mm]	ØD [mm]	Catalogue no.	Colors
5	5	3.3970.855	
6	5	3.3970.865	
6	6	3.3970.866	

Parallel connector *(set)*



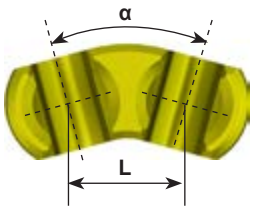
Ød [mm]	ØD [mm]	Catalogue no.	Colors
5	5	3.3970.955	
6	5	3.3970.965	
6	6	3.3970.966	

Parallel connector *(set)*



Ød [mm]	ØD [mm]	Catalogue no.	Colors
6	6	3.6294.012	

Angular connector

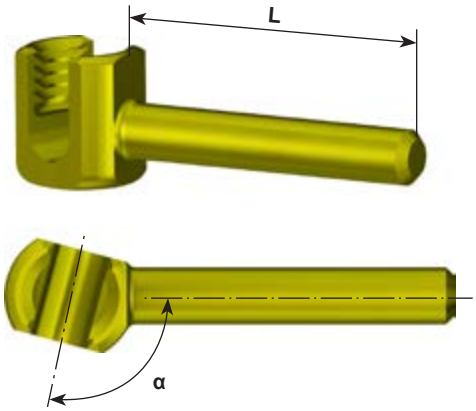


L [mm]	α	Catalogue no.
12	0°	3.6284.012
16		3.6284.016
12	10°	3.6285.012
16		3.6285.016
12	30°	3.6286.012
16		3.6286.016

Locking screw

Catalogue no.
3.6160.000

Lateral connector



L [mm]	α	Catalogue no.
15	0°	3.6281.015
20		3.6281.020
25		3.6281.025
30		3.6281.030
35		3.6281.035
15	75°	3.6282.015
20		3.6282.020
25		3.6282.025
30		3.6282.030
35		3.6282.035
15	105°	3.6283.015
20		3.6283.020
25		3.6283.025
30		3.6283.030
35		3.6283.035

Locking screw

Catalogue no.
3.6160.000

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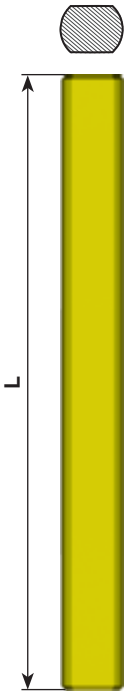
Clamp crosswise connector *(set)*

Catalogue no.
3.6287.000

Rod connector

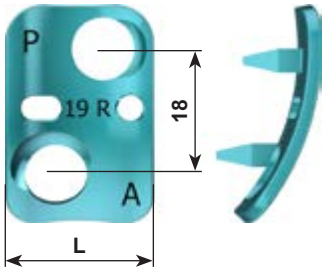


L [mm]	Catalogue no.
35	3.6289.035
40	3.6289.040
45	3.6289.045
50	3.6289.050
55	3.6289.055
60	3.6289.060
65	3.6289.065
70	3.6289.070
80	3.6289.080
90	3.6289.090
100	3.6289.100

Single-hole staple

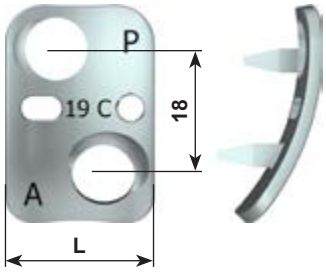
Catalogue no.
3.6291.000

Double-hole staple rostral



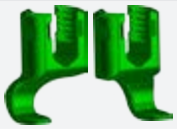
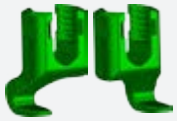
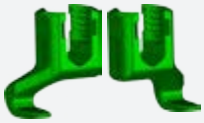
L [mm]	Catalogue no.
19	3.6292.019
21	3.6292.021
23	3.6292.023
25	3.6292.025
27	3.6292.027

Double-hole staple caudal



L [mm]	Catalogue no.
19	3.6293.019
21	3.6293.021
23	3.6293.023
25	3.6293.025
27	3.6293.027

Spinal Hooks

Small	Standard	Large
Laminar hook		
 3.6266.001	 3.6266.002	 3.6266.003
Laminar hook, narrow blade		
 3.6267.001	 3.6267.002	 3.6267.003
Laminar hook, extended body		
3.6268.001*	 3.6268.002	3.6268.003*
Laminar hook, offset		
3.6269.001 – right* 3.6269.101 – left*	 3.6269.002 – right 3.6269.102 – left	3.6269.003 – right* 3.6269.103 – left*
Laminar hook, angled blade		
3.6270.001*	 3.6270.002	3.6270.003*
Thoracic laminar hook		
	 3.6271.002	
Thoracic laminar hook, narrow blade		
	 3.6272.002	
Thoracic laminar hook, offset		
	 3.6273.002 – Small offset, right 3.6273.102 – Small offset, left	
	 3.6274.002 – Large offset, right 3.6274.102 – Large offset, left	
Pedicle hook		
 3.6275.001	 3.6275.002	 3.6275.003*
Transverse process hook		
3.6276.001 – right* 3.6276.101 – left*	 3.6276.002 – right 3.6276.102 – left	3.6276.003 – right* 3.6276.103 – left*

* available as additional item

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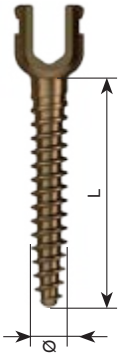
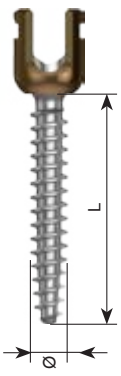
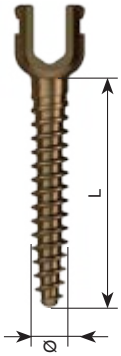
The palettes for implants presented below are not offered as sets *(they do not include implants)*.

40.8064.000 PALETTE FOR CHARSPINE2 IMPLANTS - SCREWS		Screw diameter	Size L	No. of sockets
	Monoaxial screws 	4.5	25	2
			30	2
			35	2
			40	2
			45	2
			50	2
		5.0	35	2
			40	2
			45	2
			50	2
			55	2
			60	2
		5.5	30	8
			35	8
			40	8
			45	8
			50	8
			55	8
		6.0	35	8
			40	8
			45	8
			50	8
			55	8
			60	8
		6.5	35	6
			40	6
			45	6
			50	6
			55	6
			60	6
		7.5	35	6
			40	6
			45	6
			50	6
			55	6
			60	6
		8.5	50	2
			55	2
			60	2
			70	2
			80	2
			90	2
		9.5	50	2
			55	2
			60	2
			70	2
			80	2
			90	2
	Polyaxial screws 	5.5	30	4
			35	4
			40	4
			45	4
			50	4
			55	4
		6.0	35	4
			40	4
			45	4
			50	4
			55	4
			60	4
		6.5	35	6
			40	6
			45	6
			50	6
			55	6
			60	6
		7.5	35	6
			40	6
			45	6
			50	6
			55	6
			60	6

40.8119.000 PALETTE SMALL FOR CHARSPINE2 IMPLANTS - SCREWS		Screw diameter	Size L	No. of sockets
	Monoaxial, polyaxial and uniplanar screws 	5.0	30	6
			35	6
			40	6
			45	6
			50	5
		5.5	30	6
			35	6
			40	6
			45	6
			50	5
		6.0	35	6
			40	6
			45	6
			50	6
			55	6
			60	5
		6.5	35	6
			40	6
			45	6
			50	6
			55	6
			60	5

MODULAR PALETTE FOR CHARSPINE2 IMPLANTS - CONNECTORS 1 *(STANDARD CONFIGURATION)*		
		**40.8065.000** Palette for CHARSPINE2 implants - Connectors 1
		**40.8078.000** Exchangeable module 1
		**40.8080.000** Exchangeable module 3

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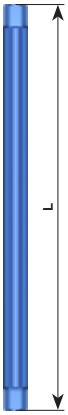
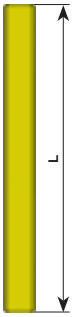
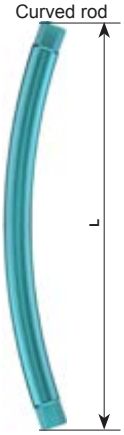
40.8065.000 Palette for CHARSPINE2 implants - Connectors 1	Implant type	Size	No. of sockets
		L-40	2
		L-50	2
		L-60	2
		L-70	2
		L-80	2
		L-90	2
		L-100	2
		L-120	4
		L-160	4
		L-200	4
		L-220	4
		L-260	4
		L-300	2
		L-360	2
		L-460	2
	Rod connectors 	L-60	2
		L-80	2
		L-100	2
	Locking screws 	-	28
	Axial connector 	6/6	1
	Parallel connector 	6/6	1
	Clamp crosswise connector 	-	4

EXCHANGEABLE MODULES – IMPLANT SOCKETS CONFIGURATION

40.8078.000 Exchangeable module 1	Implant type	Size	No. of sockets
	Curved rod 	L-35	1
		L-40	1
		L-45	1
		L-50	1
		L-55	1
		L-60	1
		L-65	1
		L-70	1
		L-75	1
		L-80	1
		L-85	1

40.8080.000 Exchangeable module 3	Implant type	Size	No. of sockets
	Crosswise connector solid 	L-14	1
		L-15	1
		L-16	1
		L-17	1
		L-18	1
		L-19	1
		L-20	1
	Crosswise connector regulated *(monoaxial)* 	XS	1
		S	1
		M	1
		L	1
		XL	1
	Lateral connector *(polyaxial)* 	XS	1
		S	1
		M	1
		L	1
		XL	1

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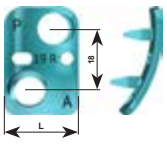
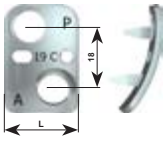
MODULAR PALETTE FOR CHARSPINE2 IMPLANTS - CONNECTORS 2 *(STANDARD CONFIGURATION)*		
		**40.8066.000** Palette for CHARSPINE2 implants - Connectors 2
		**40.8081.000** Exchangeable module 4
		**40.8079.000** Exchangeable module 2

EXCHANGEABLE MODULES – IMPLANT SOCKETS CONFIGURATION

40.8081.000 Exchangeable module 4	Implant type	Size	No. of sockets
	Angular connector 	L-12	1
		L-16	1
		10° L-12	1
		10° L-16	1
		30° L-12	1
		30° L-16	1
	Lateral connector 	L-15	1
		L-20	1
		L-25	1
		L-30	1
		75° L-15	1
		75° L-20	1
		75° L-25	1
		75° L-30	1
		105° L-15	1
		105° L-20	1
		105° L-25	1
		105° L-30	1

40.8079.000 Exchangeable module 2	Implant type	Size	No. of sockets
	Single-hole staple 	-	8
	Double-hole staple rostral 	L-19	2
		L-21	1
		L-23	1
		L-25	1
		L-27	1
	Double-hole staple caudal 	L-19	2
		L-21	1
		L-23	1
		L-25	1
		L-27	1

It is possible to change the configuration of modules included into palettes according to an individual order.

CHARSPINE system 2

TITANIUM ALLOY Ti

40.8077.000 Palette for CHARSPINE2 implants - Hooks		Implant type	Variant	No. of sockets
		Laminar hook		6
				6
				6
		Laminar hook, narrow blade		6
				6
				6
		Laminar hook, extended body	-	2
		Laminar hook, offset	Right	2
			Left	2
		Laminar hook, angled blade	-	2
		Thoracic laminar hook	-	3
		Thoracic laminar hook, narrow blade	-	3
		Thoracic laminar hook, narrow blade	Right	3
			Left	3
		Thoracic laminar hook, large offset	Right	3
			Left	3
		Pedicle hook		2
				2
		Transverse process hook	Right	3
			Left	3

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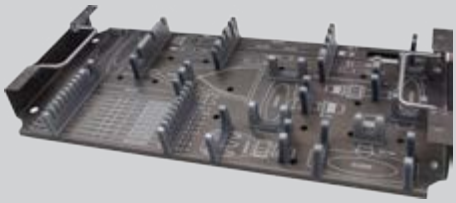
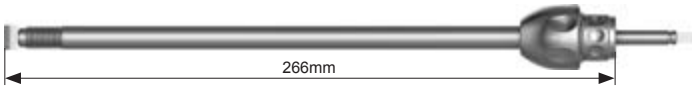
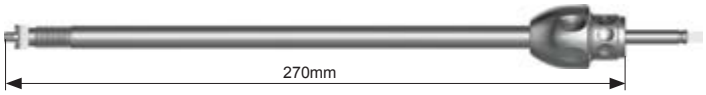
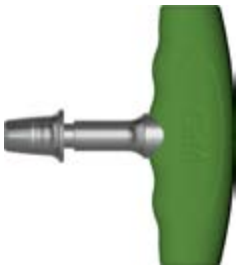
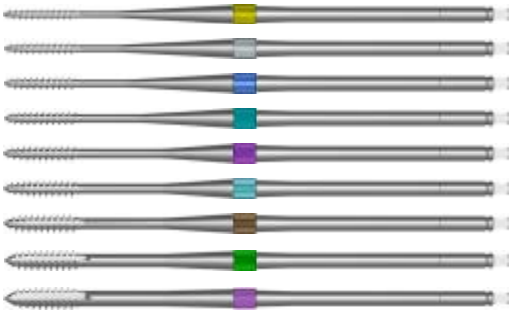
III. INSTRUMENTS

III.1. INSTRUMENT SET FOR CHARSPINE2 SPINE STABILIZER BASIC [40.8060.000]

INSTRUMENT SET FOR CHARSPINE2 SPINE STABILIZER BASIC 40.8060.000				
No.		**Name**	**Catalogue no.**	**Pcs.**
1		Stand for CHARSPINE2 instrument set module 1	40.8063.100	1
2	Screwdriver tip T15 is intended to be used only with T-type torque handle 3.5Nm **[40.8088.000]**. It is used to screw the locking screws into crosswise, axial and parallel connectors.	Screwdriver tip T15	40.8110.000	1
3	 Wrench for monoaxial screws is used for insertion and mounting of CHARSPINE2 monoaxial transpedicular screws. It is intended for use with T-type or oval head ratchet handle.	Wrench for monoaxial screws	40.8089.000	1
4	 Wrench for polyaxial screws is used for insertion and mounting of CHARSPINE2 polyaxial transpedicular screws. It is intended for use with T-type or oval head ratchet handle.	Wrench for polyaxial screws	40.8090.000	1
5	 Screwdriver tip T30 is intended to be used with T-type torque handle 12Nm **[40.8087.000]**. It is used to finally lock the transpedicular screws, hooks and lateral connectors.	Screwdriver tip T30	40.8084.000	1
6	 Screwdriver T30 is used for application and initial locking of the locking screws.	Screwdriver T30	40.8111.000	1
7	 T-type ratchet handle is used for insertion with wrenches for screws and cortical taps.	T-type ratchet handle	40.8085.000	1
8	 T-type torque handle 12Nm is intended for insertion with screwdriver tip T30 **[40.8084.000]** and is used for final screwing the locking screws into the transpedicular screws, hooks and lateral connectors.	T-type torque handle 12Nm	40.8087.000	1

INSTRUMENT SET FOR CHARSPINE2 SPINE STABILIZER BASIC 40.8060.000				
No.		**Name**	**Catalogue no.**	**Pcs.**
9	 Holder for crosswise connectors is used for insertion and mounting of clamp and regulated crosswise connectors.	Holder for crosswise connectors	40.8067.000	1
10	 Holder for rod connectors is used for insertion and mounting of rod connectors *(which are mounted together with clamp connectors)*.	Holder for rod connectors	40.8076.000	1
11	 Counter wrench is used to ensure rotational stability of the implants system during final screwing into the locking screws.	Counter wrench	40.8095.000	1
12	 T-type torque handle 3.5Nm is intended to be used only with screwdriver tip T15 **[40.8110.000]** and is used for final screwing the locking screws into the crosswise, axial and parallel connectors.	T-type torque handle 3.5Nm	40.8088.000	1
13	 Oval head ratchet handle is used for insertion with wrenches for screws and cortical taps *(interchangeably with T-type ratchet handle 40.8085.000)*.	Oval head ratchet handle	40.8086.000	1
14	 Cortical taps are intended for usage with T-type ratchet handles **[40.8085.000]** or **[40.8086.000]** and may be used for tapping the vertebral arch pedicle prior to screw insertion.	Cortical tap 4.0	40.8075.040	1
15		Cortical tap 4.5	40.8075.045	1
16		Cortical tap 5.0	40.8075.050	1
17		Cortical tap 5.5	40.8075.055	1
18		Cortical tap 6.0	40.8075.060	1
19		Cortical tap 6.5	40.8075.065	1
20		Cortical tap 7.5	40.8075.075	1
21		Cortical tap 8.5	40.8075.085	1
22		Cortical tap 9.5	40.8075.095	1

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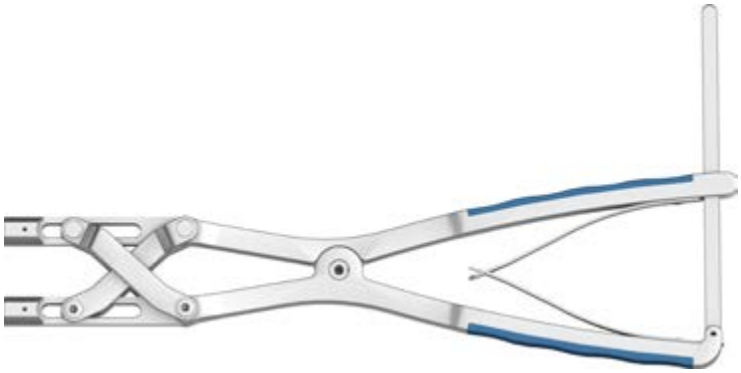
INSTRUMENT SET FOR CHARSPINE2 SPINE STABILIZER BASIC 40.8060.000				
No.		**Name**	**Catalogue no.**	**Pcs.**
23	 Template is used for selecting the size of crosswise and rod connectors.	Template	40.5248.000	1
24		Stand for CHARSPINE2 instrument set module 2	40.8063.200	1
25	 Bender is used for bending the rod in situ.	Rod bender 6.0 left	40.8091.000	1
26	 Bender is used for bending the rod in situ.	Rod bender 6.0 right	40.8092.000	1
27	 Straight pedicular trocar is used to prepare openings in the pedicle of the vertebral arch in the lumbar section of the spine.	Straight pedicular trocar	40.8072.000	1
28	 Universal pedicular trocar is used to prepare openings in the pedicle of the vertebral arch in the lumbar section of the spine.	Universal pedicular trocar	40.8071.000	1
29	 Pedicle probe is used to verify the continuity of the vertebral arch pedicle.	Pedicle probe	40.5268.000	1
30	 Thoracic pedicular trocar is used to prepare openings in the pedicle of the vertebral arch in the thoracic section of the spine.	Thoracic pedicular trocar	40.8070.000	1
31	 Holding forceps are used during derotation of the rod.	Holding forceps	40.4516.000	2
32	 Adjustable rod bender is used to bend the rod to desired shape.	Adjustable rod bender	40.8074.000	1
33	 Reduction screw device is used to break off the extended arms of reduction screws.	Reduction screw device	40.8108.000	1

INSTRUMENT SET FOR CHARSPINE2 SPINE STABILIZER BASIC 40.8060.000				
No.		**Name**	**Catalogue no.**	**Pcs.**
34	 Fork persuader is used to press the rod down the bottom of the transpedicular screw cut-out.	Fork persuader	40.8100.000	1
35	 Screw persuader is used to press the rod down the bottom of the transpedicular screw cut-out.	Screw persuader	40.8096.000	1
36	 Trocar is used to puncture the cortical layer of the vertebral arch pedicle, as a point of insertion of transpedicular screw.	Trocar	40.8073.000	1
37	 Eye wrench is used to prevent the rod from changing position while bending, and to conduct the rod derotation.	Eye wrench	40.8069.000	1
38	 Rod impactor is used to impact and press the rod down to the transpedicular screw cut-out.	Rod impactor	40.8068.000	1
39		Stand for CHARSPINE2 instrument set module 3	40.8063.300	1
40	 Impactor for staples is used for insertion and positioning of double-hole staples.	Impactor for staples	40.8098.000	1
41	 Exchangeable jaws for distraction forceps are used with distraction forceps.	Distraction forceps-jaws *(set)*	40.5769.000	1
42	 Distraction forceps are used with exchangeable jaws and are intended for procedure of vertebrae distraction.	Parallel distraction forceps	40.8093.000	1

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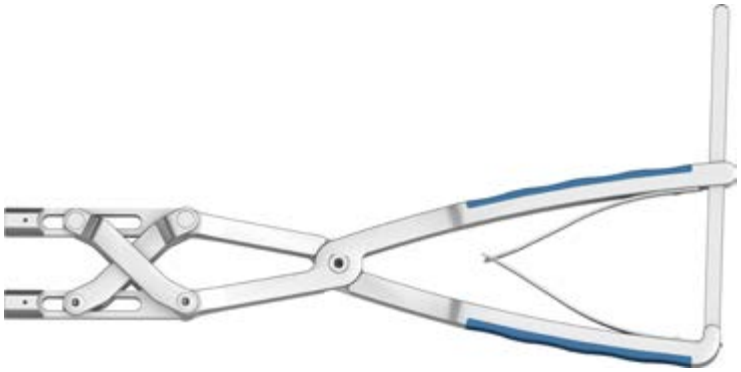
INSTRUMENT SET FOR CHARSPINE2 SPINE STABILIZER BASIC 40.8060.000				
No.		**Name**	**Catalogue no.**	**Pcs.**
43	 Compression forceps are used with exchangeable jaws and are intended for procedure of vertebrae compression.	Parallel compression forceps	40.8094.000	1
44	 Exchangeable compression jaws are used with compression forceps.	Compression forceps-jaws W-46 *(set)*	40.5768.046	1
45	 Exchangeable compression jaws are used with compression forceps.	Compression forceps-jaws W-26 *(set)*	40.5768.026	1
46	 Pliers for rod are used to grab and insert the spinal rod.	Pliers for rod	40.8109.000	
47	 Staple holder is used to insert the single-hole staples.	Staple holder	40.8099.000	

No.		**Name**	**Catalogue no.**	**Pcs.**
1		Perforated aluminum lid 1/1 595x275x15mm Gray	12.0750.200	2
2		Container solid bottom 1/1 595x275x135mm	12.0750.102	2

III.2. INSTRUMENT SET FOR CHARSPINE2 SPINE STABILIZER EXTENDED [40.8061.000]

An extended instrument set 40.8061.000 *(module 1 + module 2 + module 3 + module 4)* **consists of:**
- instruments from the basic instrument set 40.8060.000 *(module 1 + module 2 + module 3)*,
- instruments from the hooks module *(module 4)*.

INSTRUMENT SET FOR CHARSPINE2 SPINE STABILIZER EXTENDED 40.8061.000				
HOOKS MODULE *(module 4)*				
No.		**Name**	**Catalogue no.**	**Pcs.**
48		Stand for CHARSPINE2 instrument set module 4	40.8063.400	1
49	 Lateral hook holder is used to insert spinal hooks with mounting on the cylindrical part of the implant.	Lateral hook holder	40.8102.000	1
50	 Hook holder is used to insert spinal hooks with mounting on the cylindrical part of the implant.	Hook holder	40.8101.000	1
51	 Impactor for hooks is used for final impaction of spinal hook into the selected space.	Impactor for hooks	40.8103.000	1
52	 Raspatory for pedicle hooks is used to prepare space for a pedicular hook.	Raspatory for pedicle hooks	40.8107.000	1
53	 Wide raspatory for laminar hooks is used to prepare space for a laminar hook.	Wide raspatory for laminar hooks	40.8106.000	1
54	 Raspatory for laminar hooks is used to prepare space for a laminar hook.	Raspatory for laminar hooks	40.8105.000	1
55	 Narrow raspatory for laminar hooks is used to prepare space for a laminar hook.	Narrow raspatory for laminar hooks	40.8104.000	1

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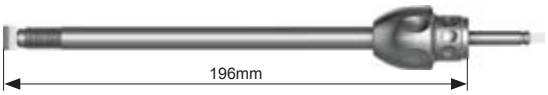
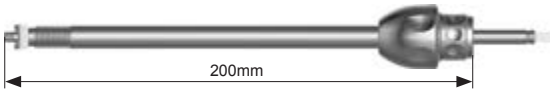
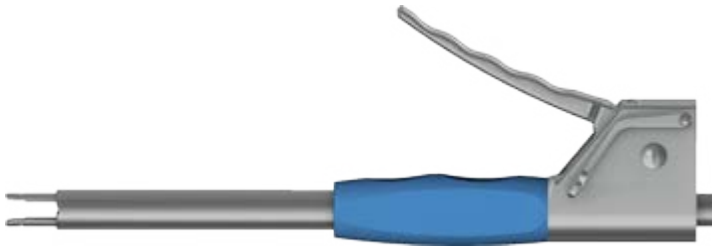
Instruments mentioned below are not included in the standard instrument set. In order to include them in the ordered instruments CHARSPINE2, please contact your local representative or ChM Sales Department.

No.		Name	Catalogue no.
1	 Wrench for monoaxial screws short is used as an alternative to the standard wrench 40.8089.000 in situations where the conditions of surgery or the surgeon's preferences require the use of shorter instrument.	Wrench for monoaxial screws short	40.8112.000
2	 Wrench for polyaxial screws short is used as an alternative to the standard wrench 40.8090.000 in situations where the conditions of surgery or the surgeon's preferences require the use of shorter instrument.	Wrench for polyaxial screws short	40.8113.000
3	 Hand hold rod cutter is used for easy cutting of rods with diameters of 6mm, 5mm and 3.5mm.	Hand hold rod cutter	40.5288.000
4	 Screw persuader is used as an alternative to the standard persuader 40.8096.000. The instrument can be handled using only one hand.	Screw persuader	40.8083.000
5	 Rod trials are used for initial rough assessment of the size and shape of the rod and to facilitate the selection of the proper size of the spinal rod, in the spinal stabilization procedures using transpedicular screws.	Rod trial 6/300	40.5246.300

IV. SURGICAL TECHNIQUE

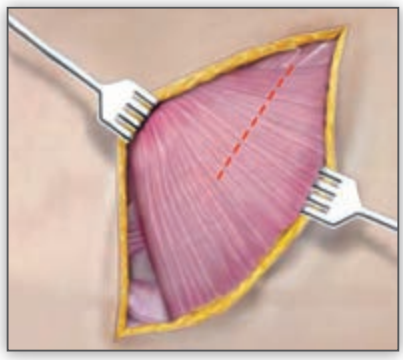
Anterior approach to thoracolumbar spine
Surgical procedures on the thoracolumbar spine by means of anterior approach are generally performed with a patient in a lateral position, with the assistance of a general or vascular surgeon.

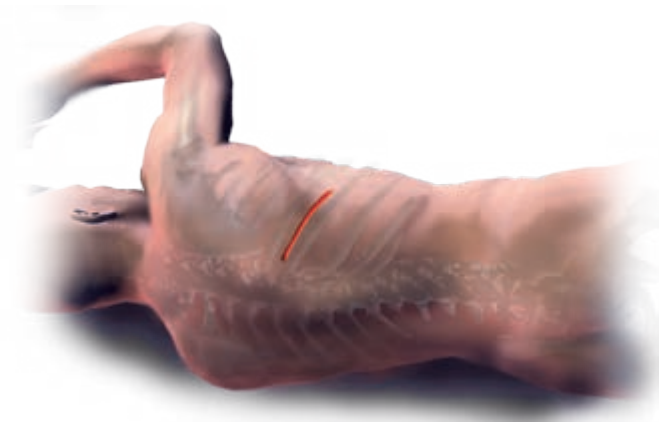
IV.1. THORACOTOMY

Thoracotomy is a standard approach for the treatment of thoracic spine disorders such as deformity, tumor or infection. In case of deformity treatment, the approach is always located on the side of the curve apex, e.g. a right-sided thoracotomy is chosen for a right-sided curve. In general, a left-sided thoracotomy is preferred, especially in the lower thoracic area, due to right-sided location of the liver which limits the operative field. However, when the upper part of the thoracic spine is concerned, some surgeons favour right-sided approach *(in cases when the spinal pathology does not dictate the side of thoracotomy)* to avoid subclavian and carotid arteries in the left superior mediastinum.

Indications
Spinal pathologies *(deformities, degenerations, fractures, tumours, infections)* that are located between T4 and T10 are an indication for a thoracotomy.

Patient positioning
In case of right-sided thoracotomy, the patient is lying on the left side on a soft, rubber mattress. The arms are positioned at elevation of 90° and with the elbows flexed. The legs are kept straight, with the right leg resting on the left leg. The symphysis and the sacrum are supported by pads to maintain the specified position.
Prior to skin incision, the side of thoracotomy and the level involved are to be confirmed. It is essential to center the incision right over the pathology place and to select the intercostal space correctly. To confirm the selected spine level, it is recommended to count the ribs and to compare the result with the radiograph.
The skin incision shall be extended from the lateral border of the paraspinous muscle up to the sternocostal joint.



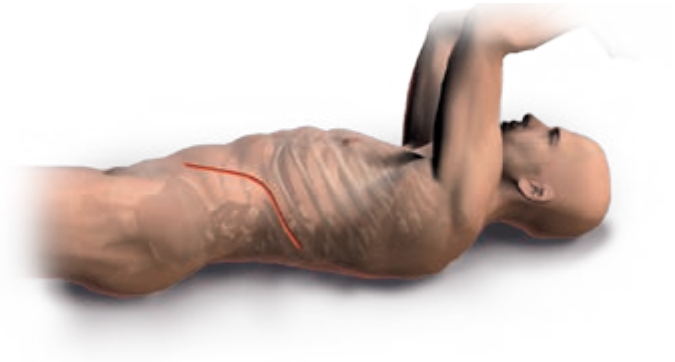


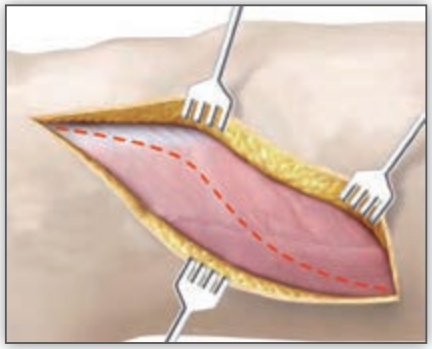
IV.2. ANTERIOR THORACOLUMBAR APPROACH

The anterior approach to thoracolumbar section may be used if there is a need of simultaneous exposure of vertebral bodies of lower thoracic and upper lumbar parts of the spine.Technically, this approach is more difficult than thoracotomy because of the diaphragm exposed and the increased risk of simultaneous exposure of the thoracic cavity and the peritoneal space. If the spine pathology does not determine the side of the approach, the access from the left side is preferred due to right-sided location of the liver.

Indications
The anterior thoracolumbar approach is recommended for spine pathologies mentioned as an indication for thoracotomy and situated between T9 and L5.

Patient positioning
The patient is placed in the right lateral decubitus position, with supports placed beneath the thorax and shoulders. The table may be slightly bent above the level of pelvis to increase the distance between pelvis and thorax.
During the operation special care should be taken to not harm the branches of the phrenic nerve, which are extending peripherally from the center towards anterolateral and posterior direction. It is recommended to make the incision around the periphery of the diaphragm to minimize the interference with its function when making the thoracoabdominal approach to the spine.
Special care should also be taken when entering the abdominal cavity.
To gain the best access to the space between T12 and L1, it is usually recommended to resect the tenth rib which allows exposure between T10 and L2.





IV.3. ANTERIOR RETROPERITONEAL APPROACH

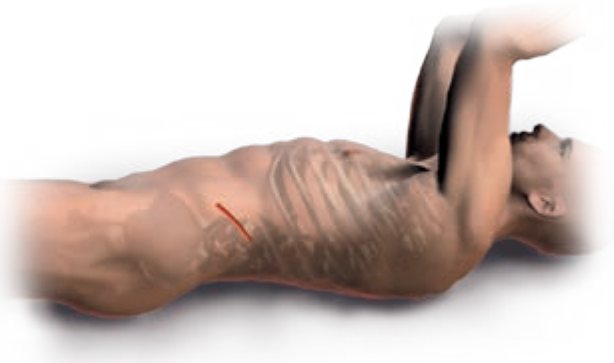
The anterior retroperitoneal approach to the lumbar vertebral bodies is a modification of the anterolateral approach commonly used by general surgeons during the sympathectomy. It allows for superior, multilevel access to the lumbar spine.

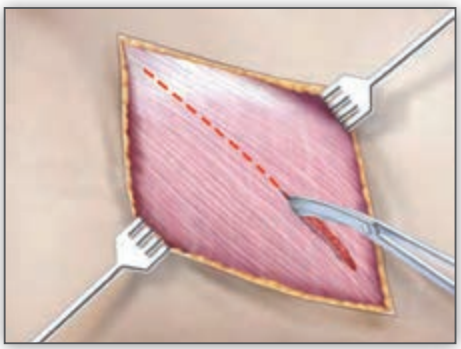
Indications
The anterior retroperitoneal approach is recommended for spine pathologies *(deformities, degenerations, fractures, tumours, infections)* situated between L2 and L5.

Patient positioning
The patient is placed in the decubitus position, in most cases on the right side. Most often, the approach is made from the left side to prevent damage to the liver and the inferior vena cava. To better expose the space between the twelfth rib and the iliac crest, the table planes may be flexed. Lower limbs are bent slightly in hips to release the tension of the psoas muscle.

The incision is to be oblique, above the twelfth rib, from the lateral border of the quadratus lumborum muscle to the lateral border of the rectus abdominis muscle, in order to allow access to the first and second lumbar vertebrae.

When the lower vertebrae *(from L3 to L5)* are exposed, the incision is to be made a few fingers below and parallel to the costal margin.





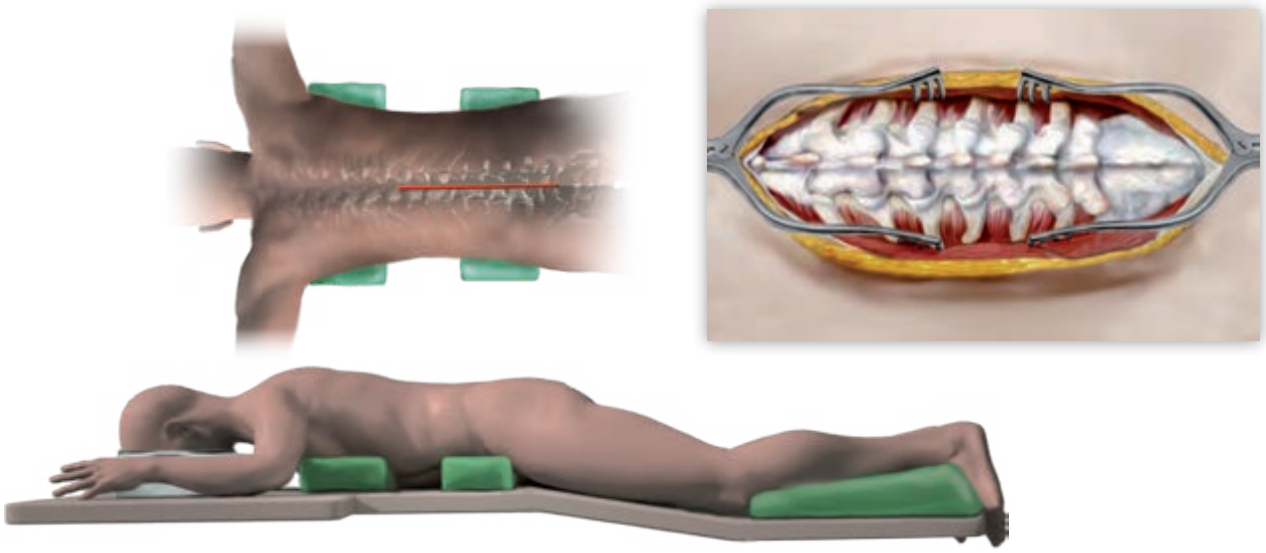
IV.4. POSTERIOR APPROACH TO THE THORACOLUMBAR APPROACH

The posterior approach to the thoracolumbar spine can be made through standard midline longitudinal incision with lateral retraction of the erector spinae in the direction of the transverse processes tips. This approach allows for access to the spinous processes, vertebral arches and joints at all levels.
The target spine level should be determined using the X-Ray control, so that the spine is unveiled only at the required segment.

Indications
The anterior approach to the thoracolumbar spine is recommended for spine pathologies *(deformities, spine canal stenoses,fractures, degenerations, tumours, infections, instabilities, herniations)* situated between T1 and L5.

Patient positioning
Patient is placed prone on rubber-foam supports. To avoid excessive pressure and pressure sores, a headrest with support for mouth, nose and eyes should be used. It is vital to avoid any pressure on the abdomen. It is crucial while decompressing the spine, as pressure on abdomen may cause vein congestion and thus excessive intraoperative bleeding.

Positioning the patient on a bending surgical table with supports with flexion of hip and knee joints allows for reduction of lumbar lordosis and easier access to posterior spine elements and spine canal structures, especially at the lumbosacral junction.



IV.5. APPROACH TO POSTERIOR SUPERIOR ILIAC SPINE

Indications
This approach is recommended when the following occur: a significant lumbopelvic *(caused by damage at S1 level resulting from trauma, tumour or infection)* or long thoracolumbosacral instrumentation of scoliosis, causing a high risk of instability of the lumbosacral connection.

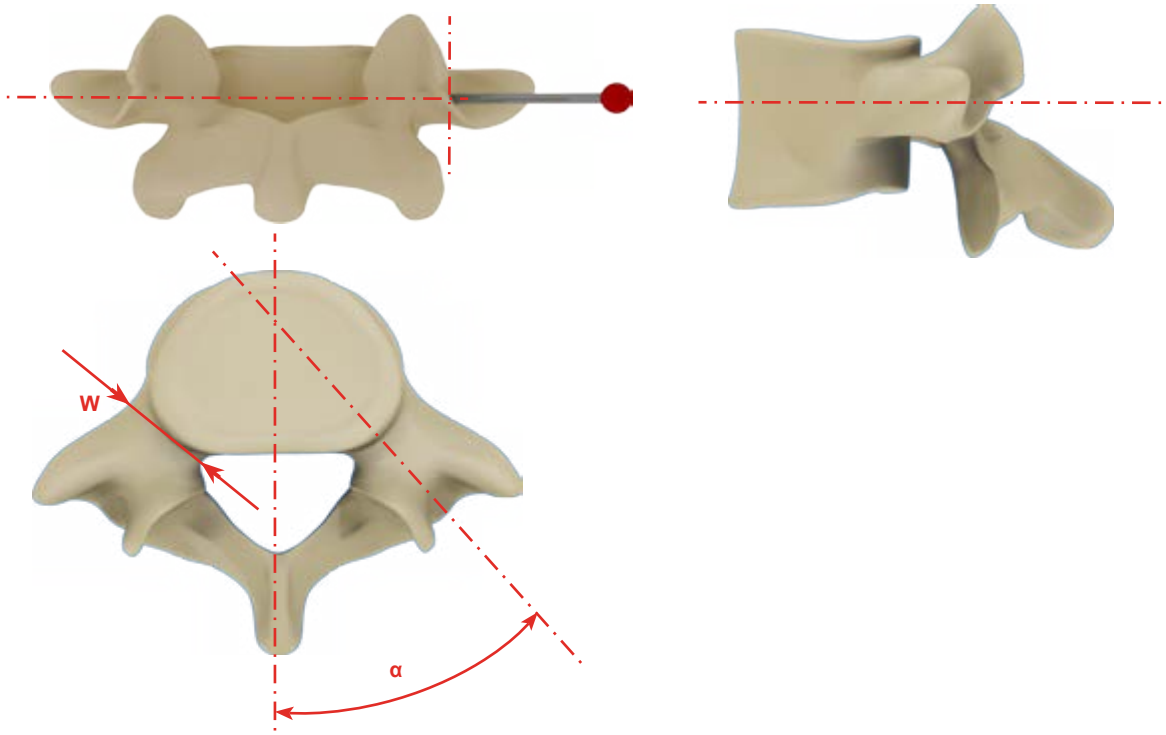
Patient positioning
Patient is positioned in the same manner as presented in section IV.4.

Screw implantation in pelvis requires access to the posterior superior iliac spine. First, the lumbosacral spine is exposed. The posterior superior iliac spine may be exposed with a separate, longitudinal skin incision, bilateral resection of the myofascial flaps and retraction in lateral and cephalad direction.

The entry point is located at the lower part of the posterior superior iliac spine. It is recommended to use osteotome *(or rongeur)* to remove a fragment of the iliac crest around the screw head or to sink the screw head in the bone to avoid any screw prominence, especially when slim patients are concerned.

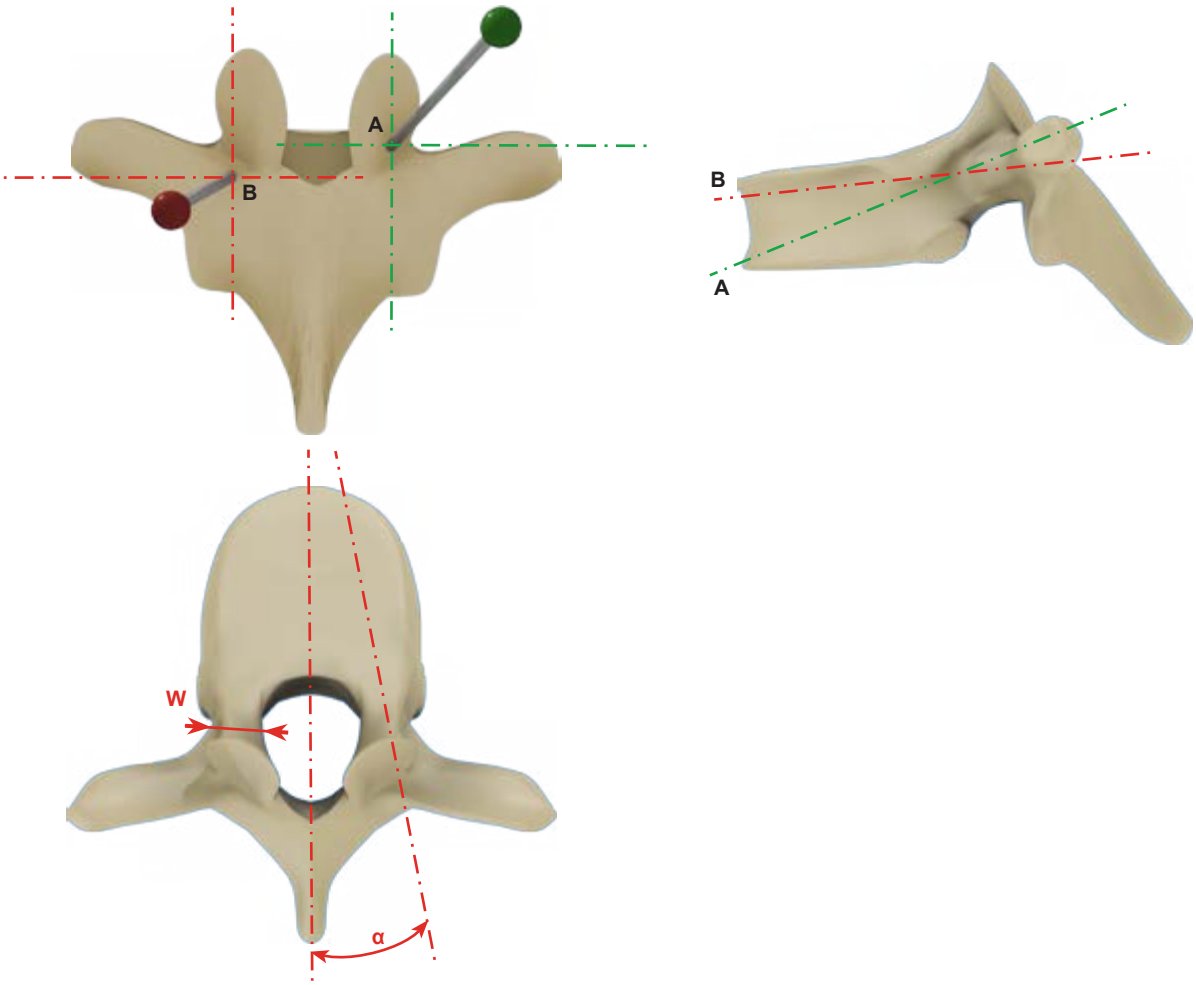
IV.6. SCREW SELECTION. PREPARATION OF THE SCREW ENTRY POINT

During transpedicular stabilization it is of vital importance to select appropriate screw diameter for specific vertebrae and to carefully choose the site and α angle of insertion.Depending on the location level, the pedicles of vertebrae arches are varied in terms of shapes and geometry *(e.g. the cross section of the vertebrae arch pedicles in the thoracic spine indicates an irregular, kidney-like shape with the medially-directed convexity)*.
Taking into consideration the above-mentioned, the initial selection of screw diameter and length has to be performed within the preoperative procedures, individually for each vertebrae on the basis of CT and X-Ray images *(in AP and lateral projections)*.
The internal dimension of the arch of a vertebrae pedicle *(W)* is of vital importance when choosing the external diameter of the transpedicular screw. It is crucial to remember that the pedicle dimensions obtained on the basis of imaging in AP projection are not real dimensions and should be treated as approximate values only. In general, the outer diameter of the screw is 2 mm smaller than the internal dimension of the vertebrae pedicle arch.



Screw insertion point is located at the intersection of a line that divides the transverse processes in half and the line along the lateral aspect of the superior articular process.

NOTICE!
The surgeon shall decide about the size of screws on the basis of CT and X-Ray imaging and intraoperative identification *(probing the pedicle)*.



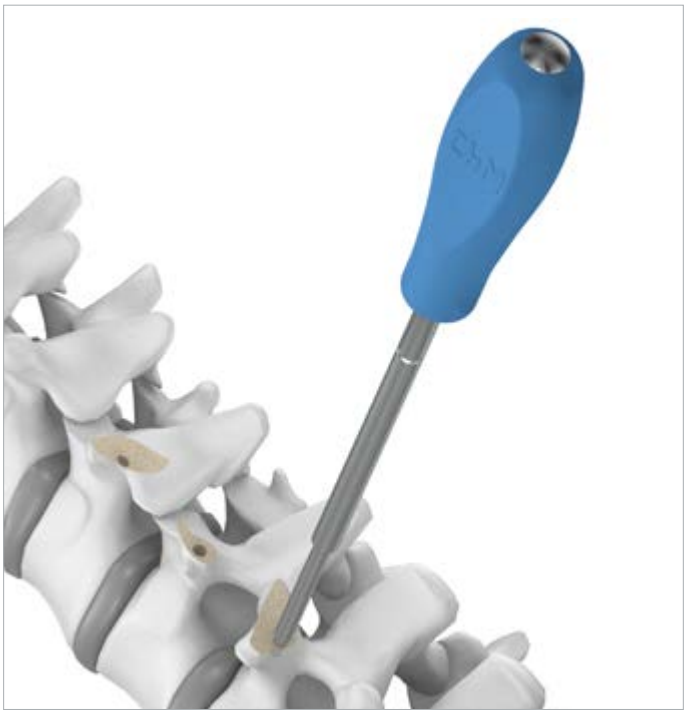
There are two alternative trajectories for insertion of screws through the thoracic vertebrae pedicles:
A – anatomical approach
B – straight approach *(direct)*

The insertion point is located at the intersection of a line in sagittal projection about 1 mm in medial direction from the lateral edge of the lamina and of a line along the transverse processes about 1 mm below the surface of the superior articular process.

NOTICE!
If anatomical approach is used, only polyaxial screws are to be used.
If straight *(direct)* approach is used, both normal and polyaxial screws may be used.

IV.7. INSERTION OF SCREWS. POSTERIOR APPROACH

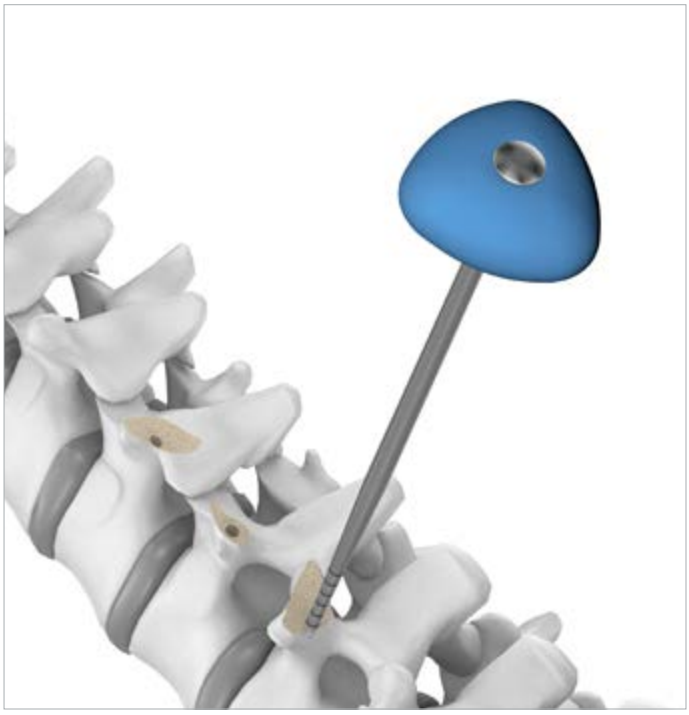
IV.7.1. PREPARATION OF VERTEBRAL ARCH PEDICLES



The point of screw insertion is prepared with a trocar **[40.8073.000]** which is used to puncture the cortical layer of the vertebral arch pedicle.

When it is necessary a bone rongeur is used to remove the upper part of the vertebral articular process at the screw insertion point, therefore the cancellous bone right under the cortical layer and the access to the vertebral arch pedicle are exposed.

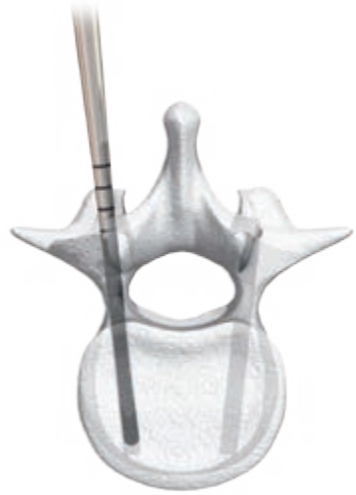
Pedicle diameter and the angle should be determined prior to the operation by means of imaging studies. It allows for later determination of depth and angle of the prepared canal and the screw diameter.

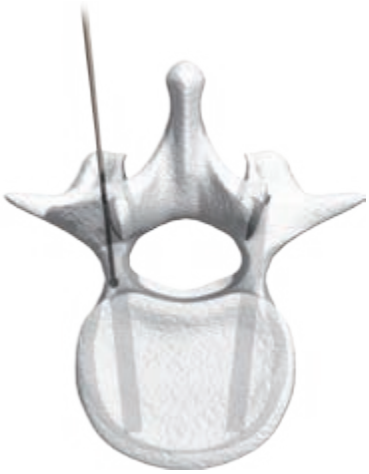


An opening for screw is prepared with the use of a pedicular trocar *(which is available as: universal [40.8071.000], straight [40.8072.000] and thoracic [40.8070.000])*.

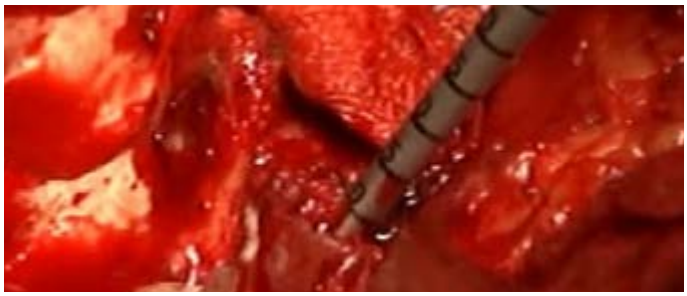
The instrument is inserted by means of delicate rotary-oscillatory movement.

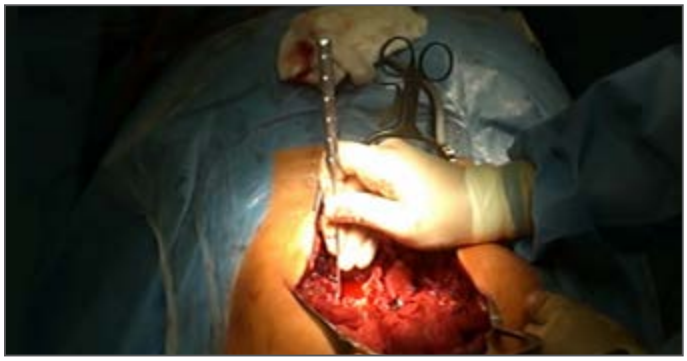
The tip should be inserted carefully, led along the interior walls of the vertebral cortical bone with the smallest resistance possible, so the vertebra walls remain undamaged.



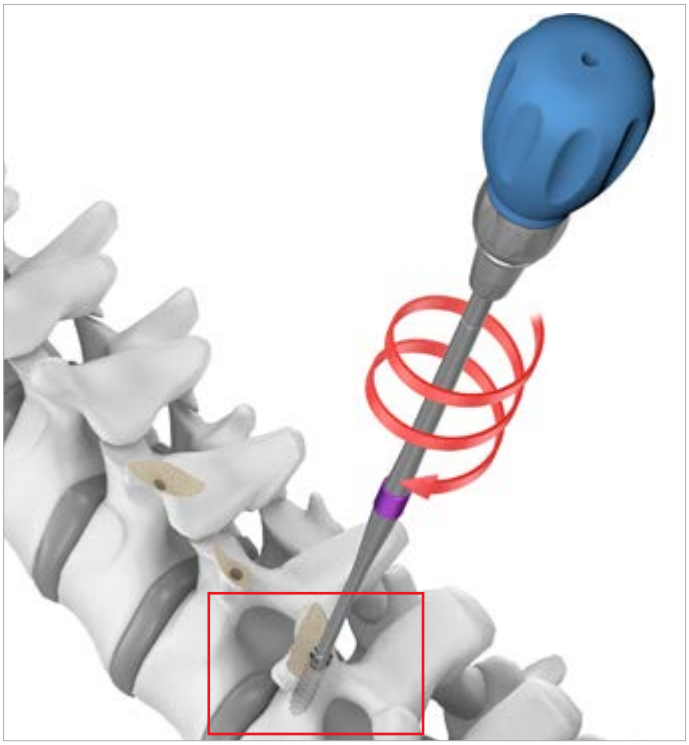


Trocar tip has marked depth indicators in five-millimeter increments to help determine the correct length of the transpedicular screw.
Identical procedure should be used while preparing the opening in the second pedicle.

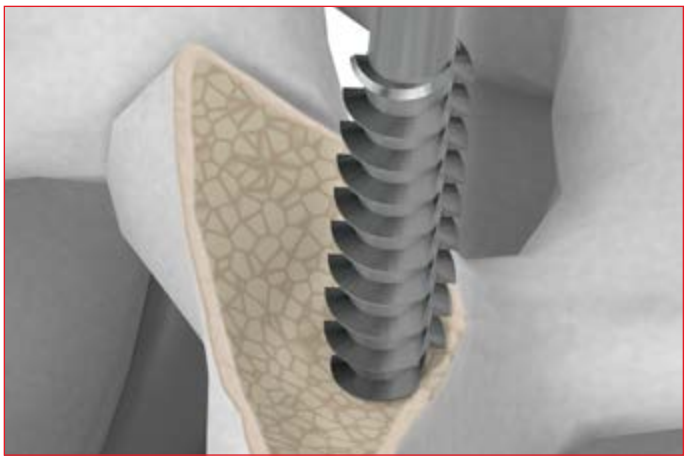




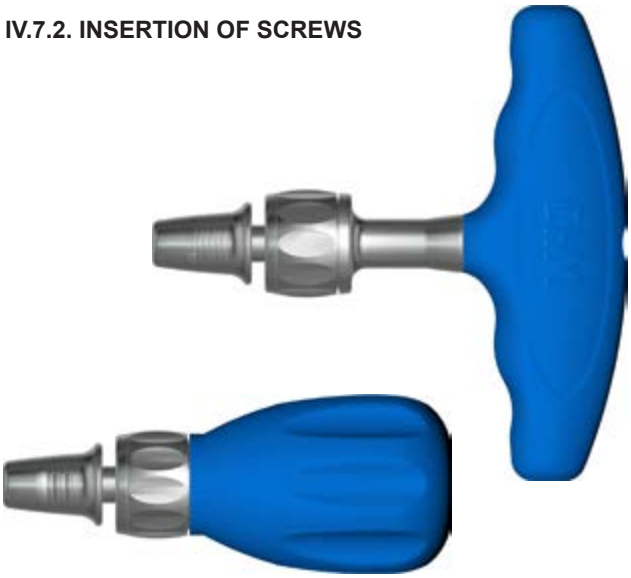
NOTE!
Prior to screw insertion, it is recommended to check the continuity of all walls of the vertebral arch pedicle with the help of the pedicle probe [40.5268].



CHARSPINE2 screws are self-tapping, therefore there is no need to tap the vertebral arch pedicle. However, if tapping is clinically required, it is possible to use taps [40.8075.040÷40.8075.095] mounted on oval head ratchet handle **[40.8086.000]** or T-type ratchet handle **[40.8085.000]**.



IV.7.2. INSERTION OF SCREWS



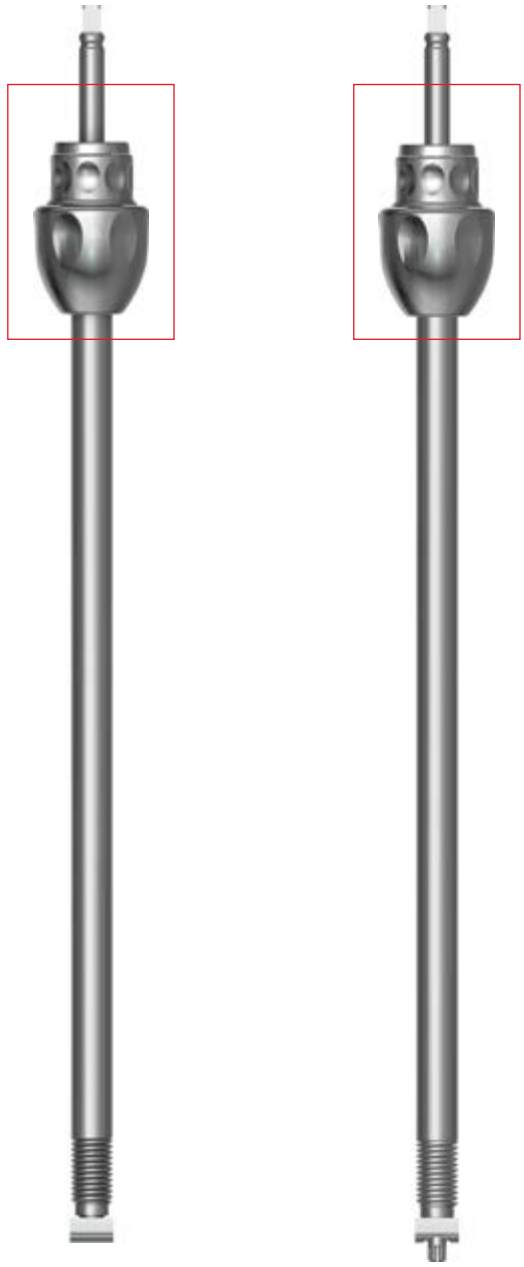
Wrenches for monoaxial **[40.8090.000]** and polyaxial screws **[40.8089.000]** are intended to be mounted on:

- T-type ratchet handle **[40.8085.000]**,
- oval head ratchet handle **[40.8086.000]**.

Monoaxial and polyaxial wrenches have a ratchet mechanism that prevents any spontaneous loosening of the tip-screw connection during the transpedicular screws insertion.

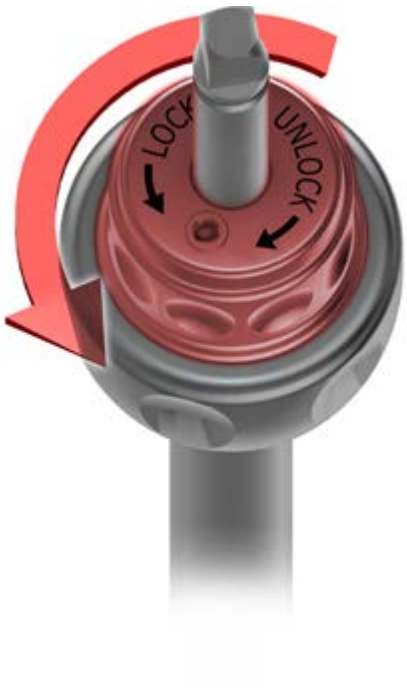
To mount the transpedicular screw on the tip of the wrench for monoaxial or polyaxial screws, set the smaller knob of the wrench onto the LOCK position *(counterclockwise)*.

This setting activates the ratchet mechanism inside the knob body.



Wrench for monoaxial screws
[40.8089.000]

Wrench for polyaxial screws
[40.8090.000]

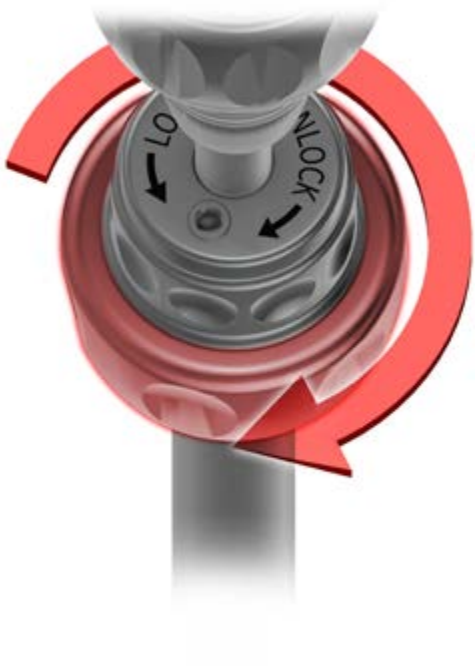


Square end of the wrench is mounted in the quick coupling end of the handle **[40.8085.000]** or **[40.8086.000]**.

Then an appropriate length and diameter of the transpedicular screw *(mono- or polyaxial)* is selected.

The tip is inserted all the way into the screw channel:

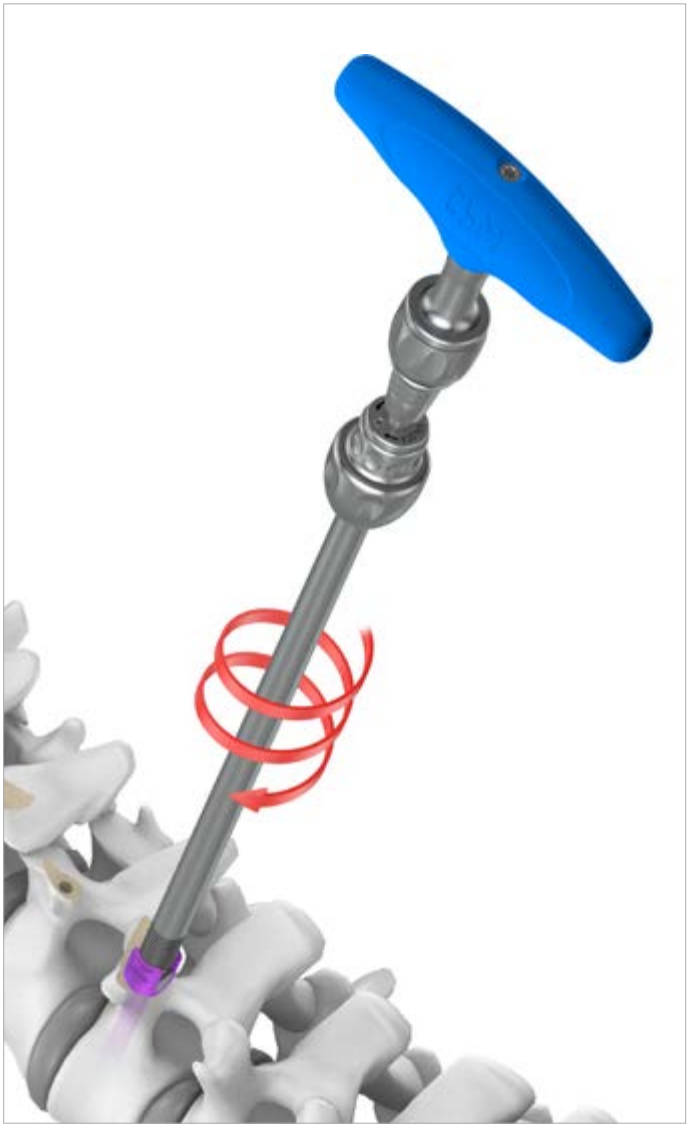
- in case of monoaxial screws a tip of wrench for monoxial screws **[40.8089.000]** is to be used.
- in case of polyaxial screws a tip of wrench for polyaxial screws **[40.8090.000]** is to be used.



By turning the larger knob in a clockwise direction, screw the threaded, external wrench sleeve all the way until the tip is completely seated at the bottom of the channel.

While screwing in the wrench sleeve, the clicks of a ratchet mechanism are audible.

The LOCK position of the mechanism prevents sleeve thread from loosening.

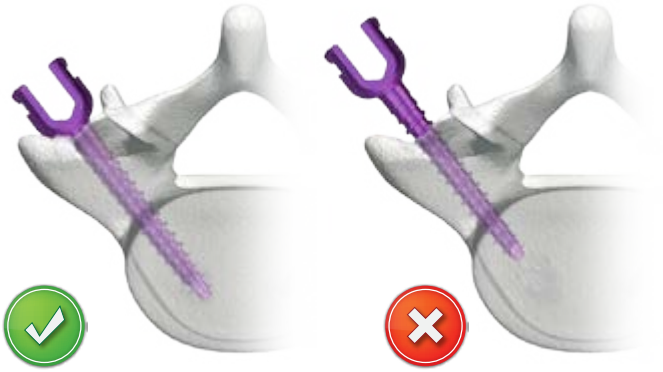


The screw mounted on a wrench is inserted into an opening prepared beforehand.

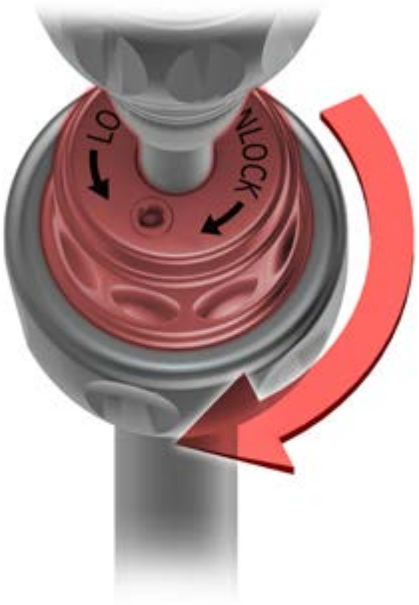
Screw insertion should be controlled in two planes with the help of X-Ray control.

NOTICE:
Remember that precise positioning of the screws is realised by screwing in, and not by screwing out.

Moving back the screw may result in loss of connection stability and may necessitate the use of a larger diameter screw.



NOTICE:
The core of the transpedicular screw is strengthened in the vicinity of its head.
To reduce the potential risk of screw breakage, it is necessarry to screw it all the way in so the whole thread is in the bone.



To dismount the wrench set the smaller knob into the UNLOCK position *(in a clockwise direction)*.
This setting allows for disconnection of the ratchet mechanism and for removal of the wrench sleeve from the transpedicular screw head.

IV.7.3. ROD SHAPING

Having inserted the screws, a rod of appropriate length to the instrumented part of the spine should be selected.

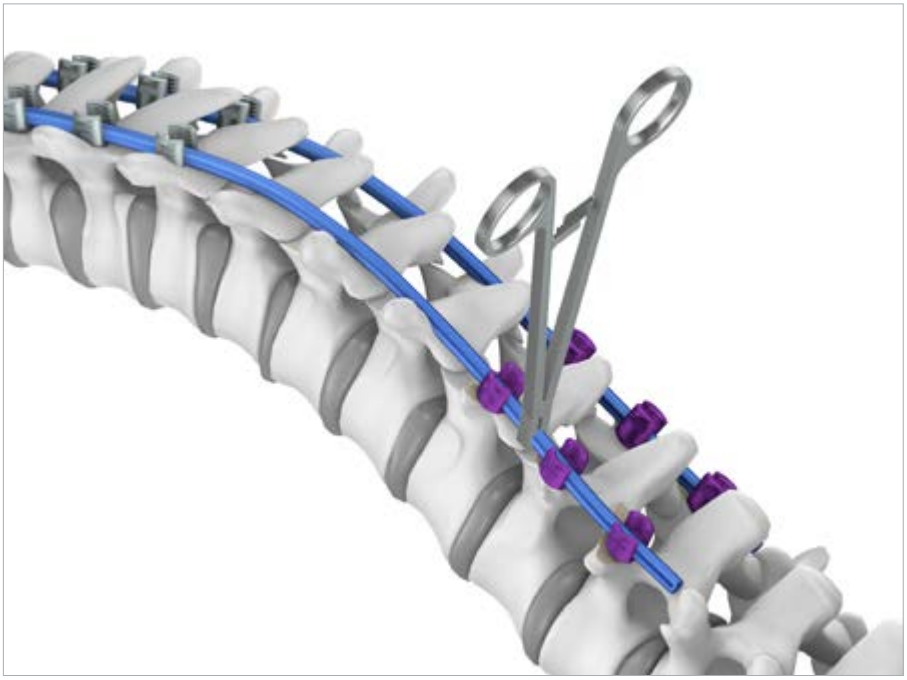
In order to determine the approximate length and the desired shape of the rod, rod trial [40.5246.300] can be used.

To achieve the desired spine curvature *(e.g. lordosis or kyphosis)*, the rod should be appropriately shaped. Shaping is performed with the help of adjustable rod bender **[40.8074.000]**

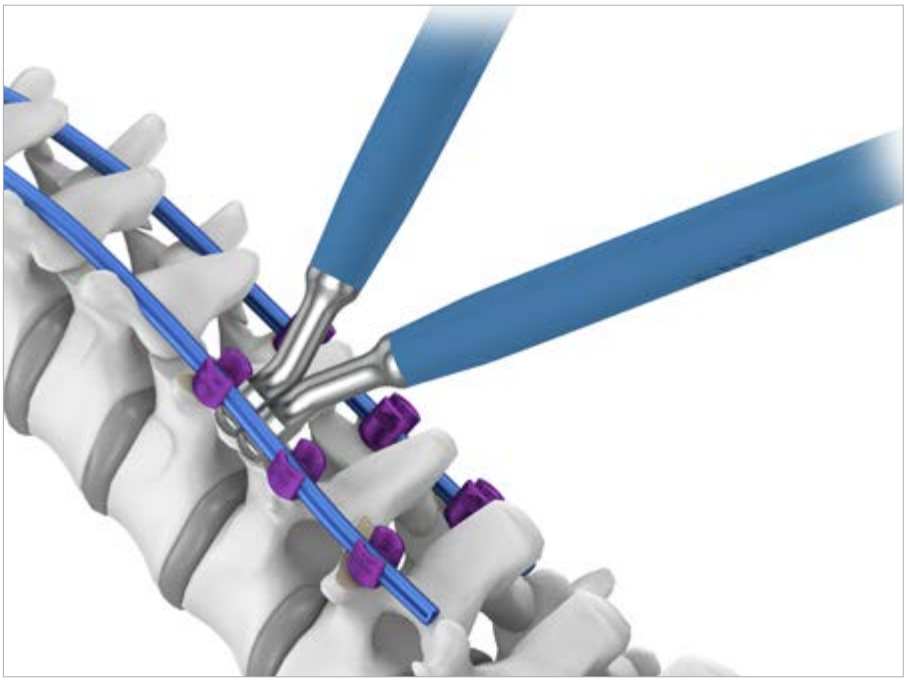
To secure the rod against movement during shaping, one of its hexagonal ends should be inserted in and held by the eye wrench **[40.8069.000]**.

CHARSPINE2 system allows the usage of rods of two types of rigidity:

1.		Rod Ø6 made of titanium alloy in accordance with ISO 5832-3/ASTM F136	standard rigidity
2.		Rod Ø6 made of cobalt alloy in accordance with ISO 5832-12/ASTM 1537	very high rigidity



Appropriately shaped rods are inserted into cut-outs of transpedicular screws with the help of pliers for rod **[40.8109.000]**.



To correct the shape of the rod in situ, use the rod benders - right **[40.8092.000]** and left **[40.8091.000]**.

If necessary, cut the rod to the desired length with the use of hand held rod cutter **[40.5288]**.

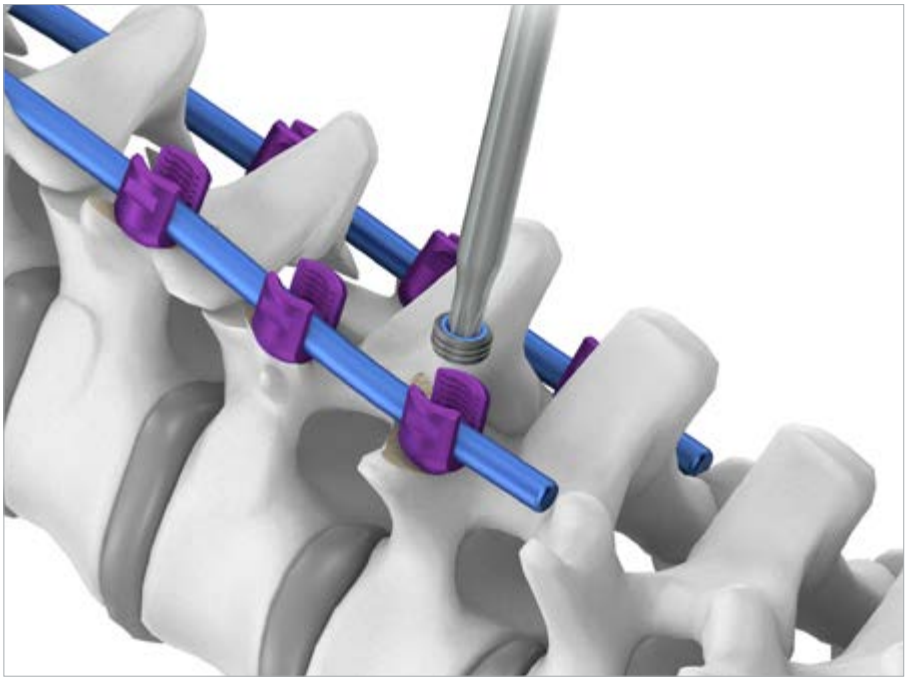
Hand hold rod cutter is a non-standard instrument and is not included into the CHARSPINE2 instrument sets.

IV.7.4. ROD FIXATION

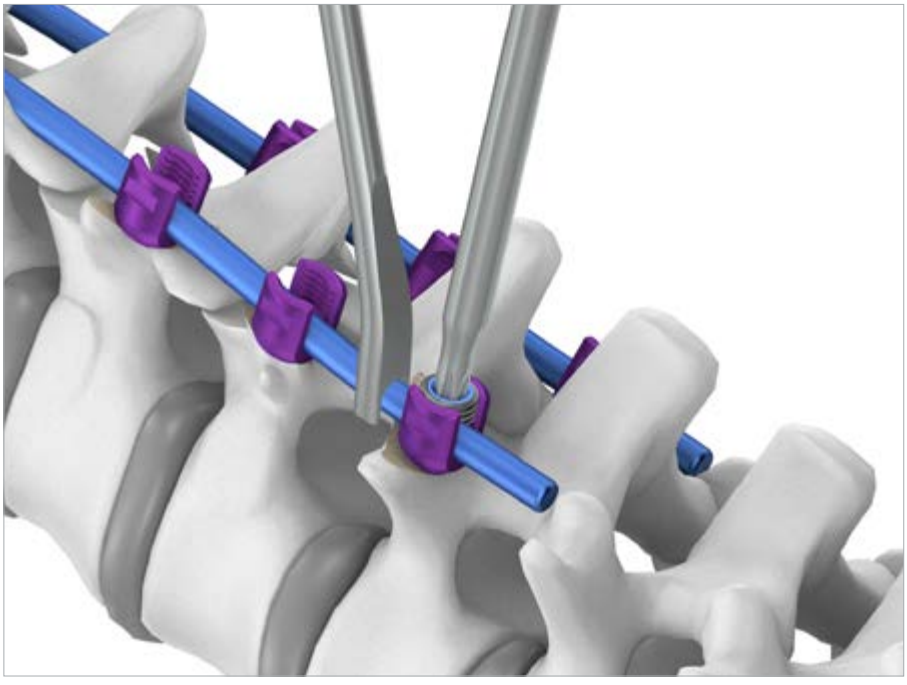
The rod is locked by inserting the locking screw **[3.6160.000]** into the transpedicular screw head.

The locking screw may be mounted on the screwdriver tip only from the upper side of the screw *(the locking screw design eliminates any errors related to the mounting)*.

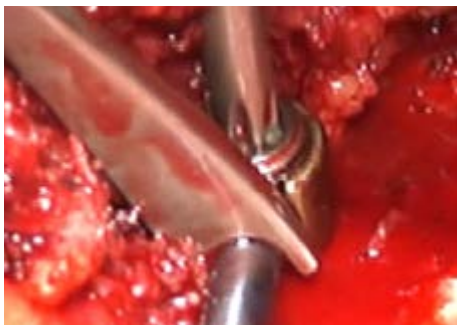
The upper surface of the screw is coloured to allow for easier identification.

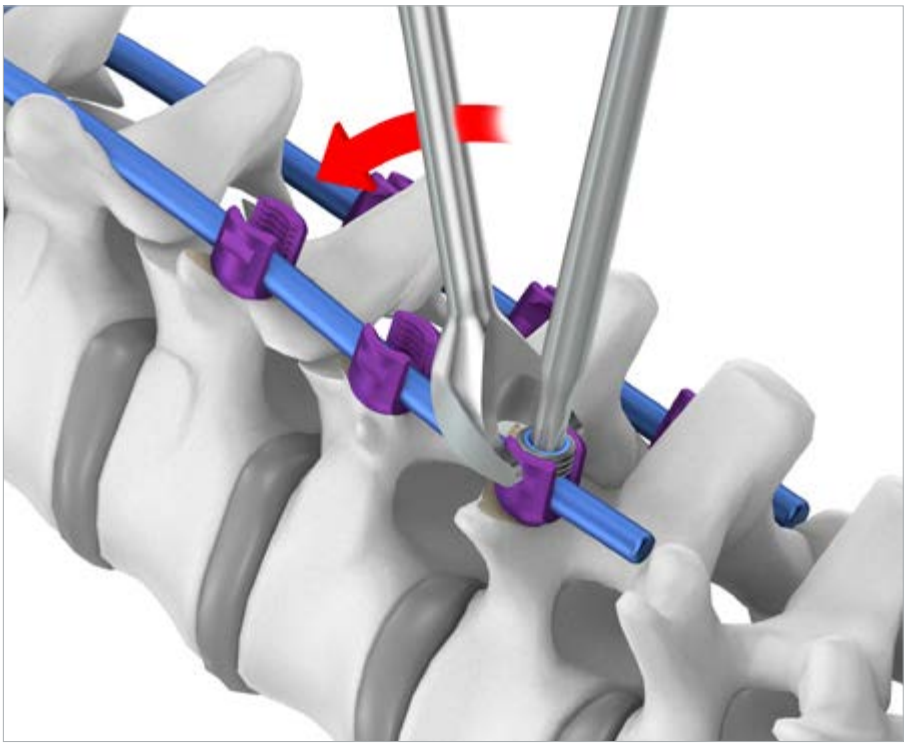


The locking screw is mounted on the tip of the screwdriver T30 **[40.8111.000]**, then it is inserted into the cut-out on the screw head and screwed in slightly in a clockwise direction, simultaneously gently pressing the rod to the screw cut-out bottom.



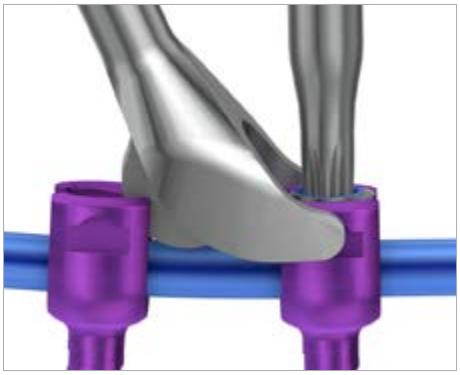
In case of difficulties when pressing the rod to the screw bottom cut-out, it is possible to use rod impactor **[40.8068.000]**.

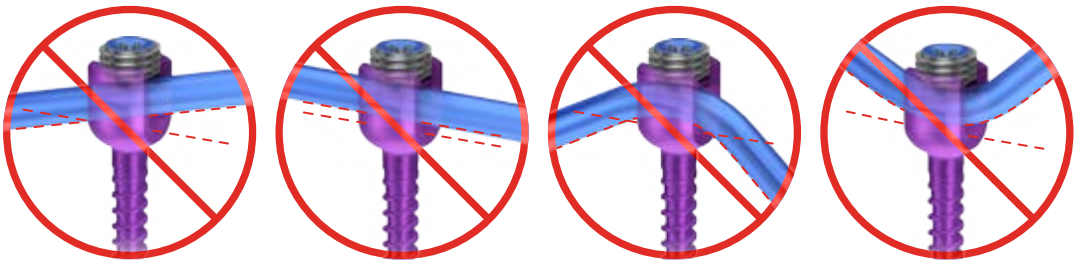




To press the rod to the screw bottom cut-out it is possible to use also fork persuader **[40.8100.111]**.

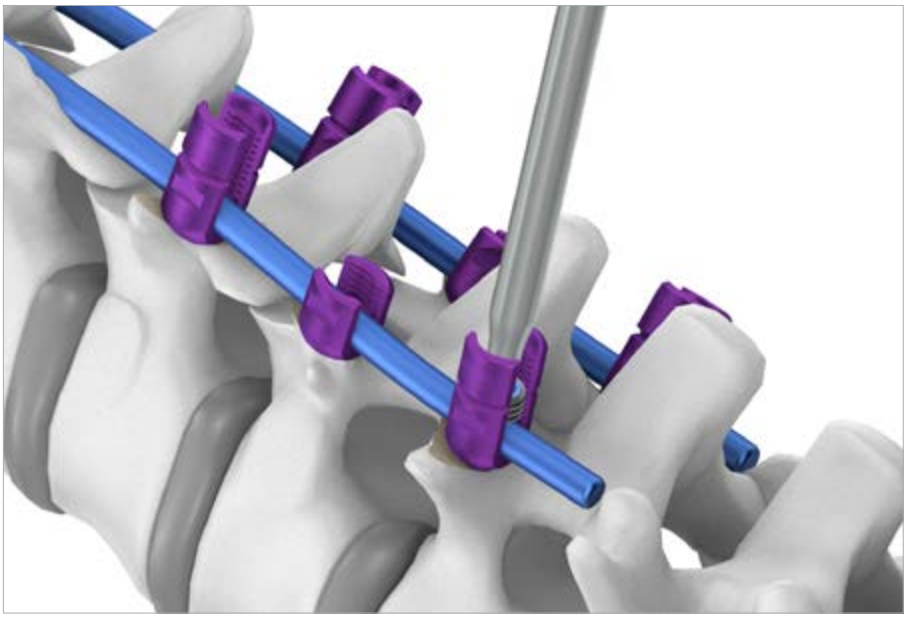
The fork persuader **[40.8100.000]** is of special design that allows its use even when the adjacent screws are very close to each other.



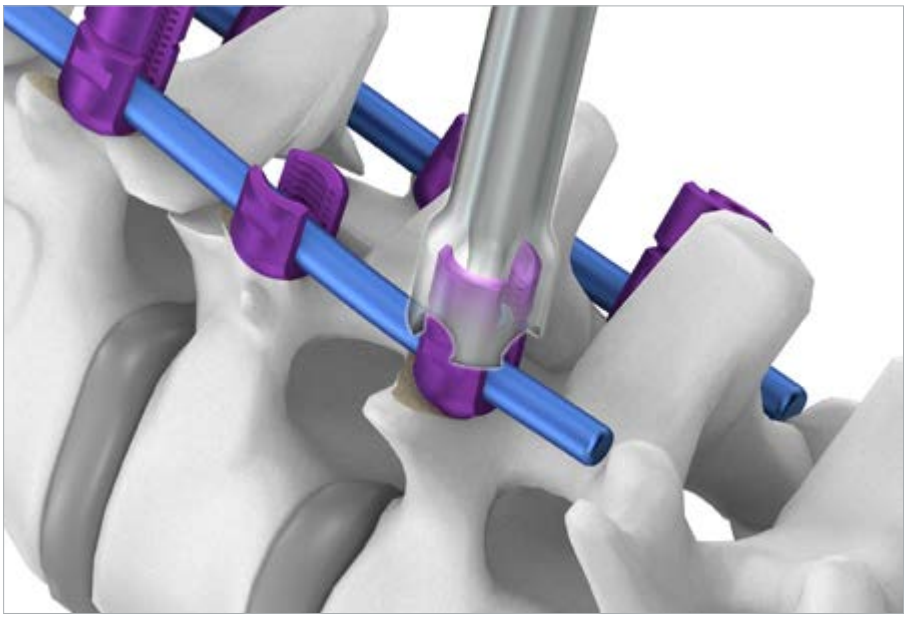


NOTICE:
It is necessary to make sure that the rod and locking screw are completely mounted on the bottom of the screw head:
- **the rod must by tangent to the cut-out bottom in the screw head,**
- **the upper part of the locking screw** *(in blue)* **should flush with the upper part of the screw head.**

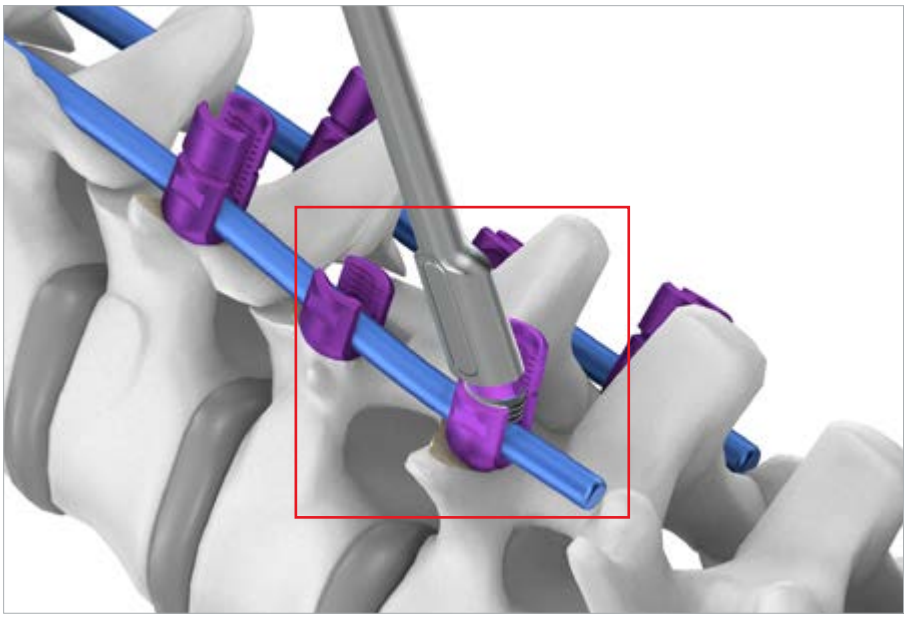
It is necessary to avoid the following:
- **the rod is not placed horizontally in the screw head,**
- **the rod is high and does not adhere to the bottom of the screw head cut-out,**
- **the screw is embedded in the place of rod bending** *(on the convexity or concavity of the arch)***.**



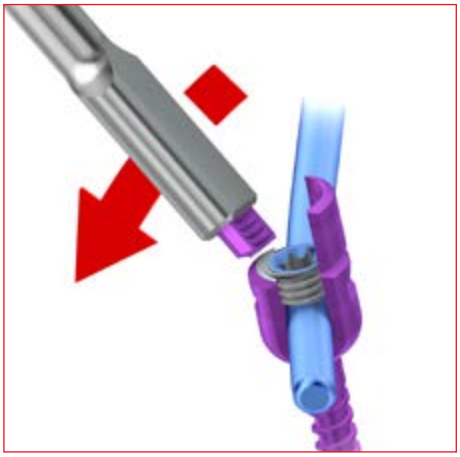
When the osteosynthesis covers more than three vertebrae, there is a risk that the rod may not fit to all screws cut-outs. In such case reduction screws are of help *(with prolonged, breakable head arms)*. Alternative positioning of a few reduction screws allows for easy pressing the rod with a locking screw into the desired position.



NOTICE:
When the long arms spread while inserting the locking screw, first put the counter wrench [40.8095.000] on the screw head and press the rod, then screw in the locking screw until the rod is completely pressed to the screw head bottom.

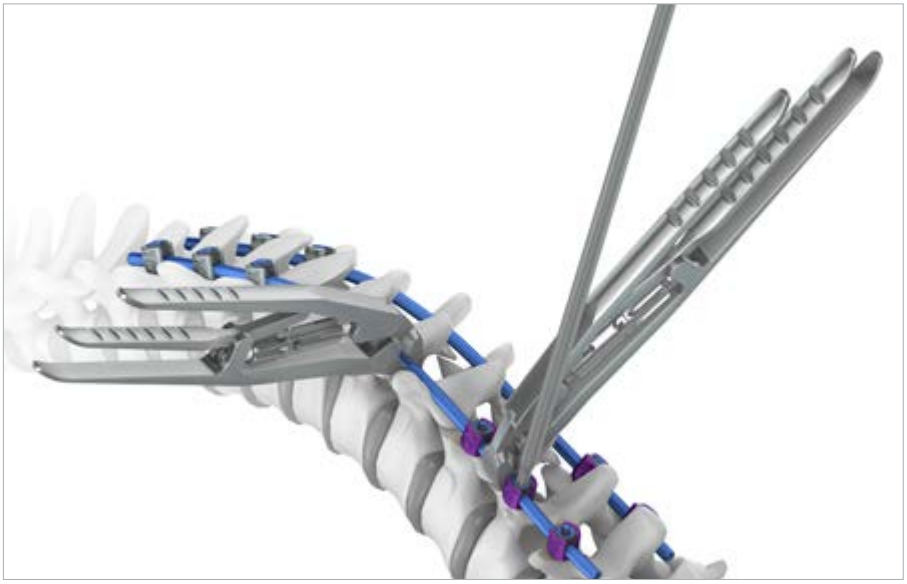


Screws arms are broken off at the end of the surgery with the use of reduction screw device **[40.8108.000]**.



NOTICE:
The abovementioned procedure may cause excessive reduction of screws *(and vertebrae)***; to avoid this it is necessary to correct the rod bending in situ.**

The use of polyaxial screws allows for adjusting the screw head position in relation to the rod, especially when the screws are not parallel. In this manner the connection achieves greater stability and there is no need for complicated rod bending. It is possible to tilt the screw head from the axis by ±22.5° in each and every direction.



It is possible to use the holding forceps **[40.4516.000]** during the procedure of rod derotation.

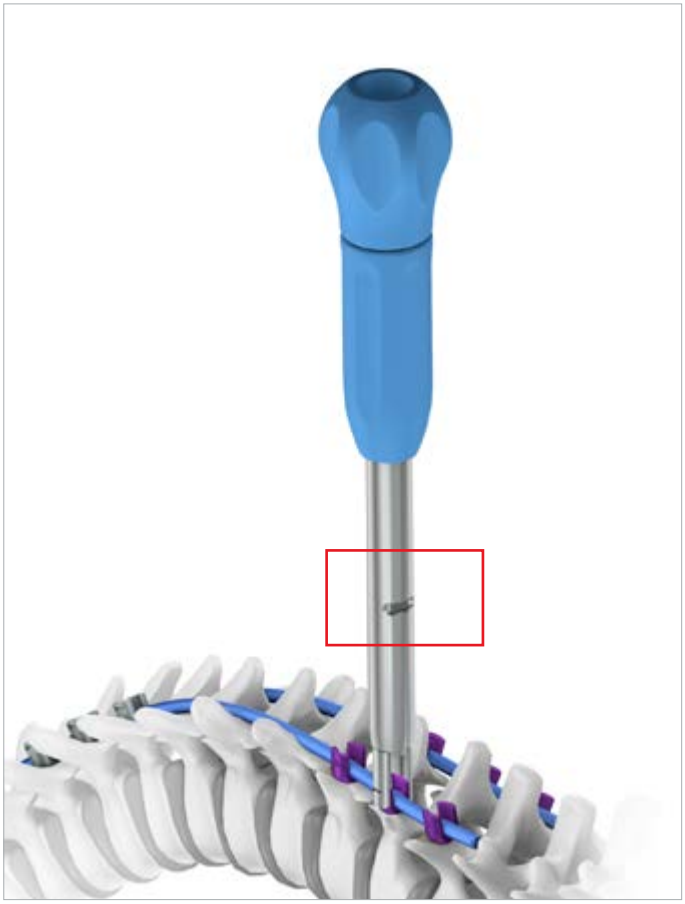
In such case, having established the desired rod position, the rod should be locked to maintain its position.

This allows for the next stage to be performed - the reposition of vertebrae.

At this stage it is possible to perform:

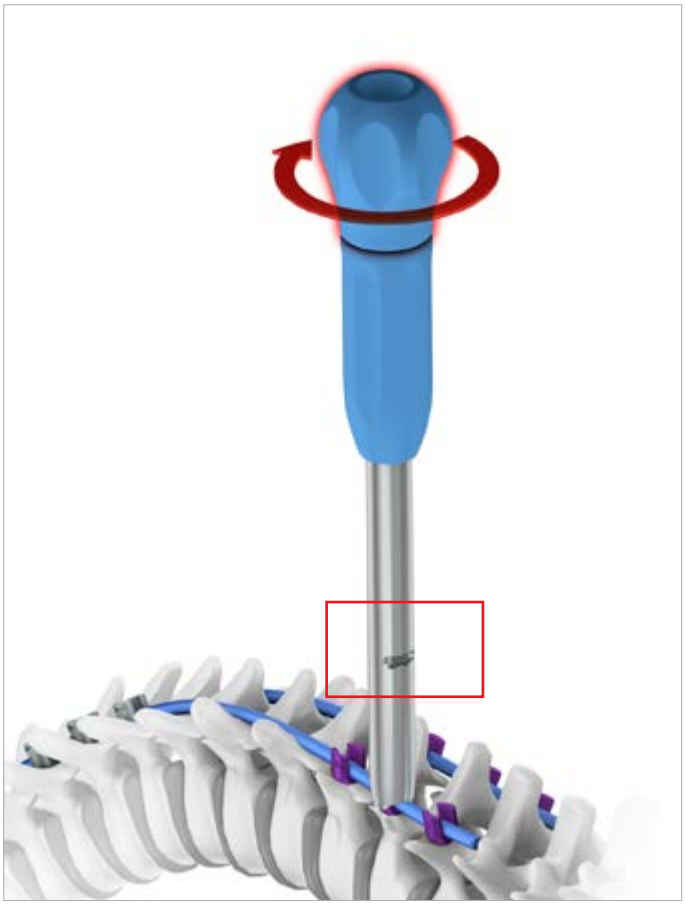
- the vertebrae distraction with the use of parallel distraction forceps **[40.8093.000]**,
- the vertebrae compression with the use of parallel compression forceps **[40.8094.000]**.

NOTICE:
A proper shaping of rods is a crucial stage of surgery allowing for good vertebrae reposition.



If more force is necessary to impact the rod into the bottom of the transpedicular screw cut-out, it is possible to use screw persuader **[40.8096.000]**.

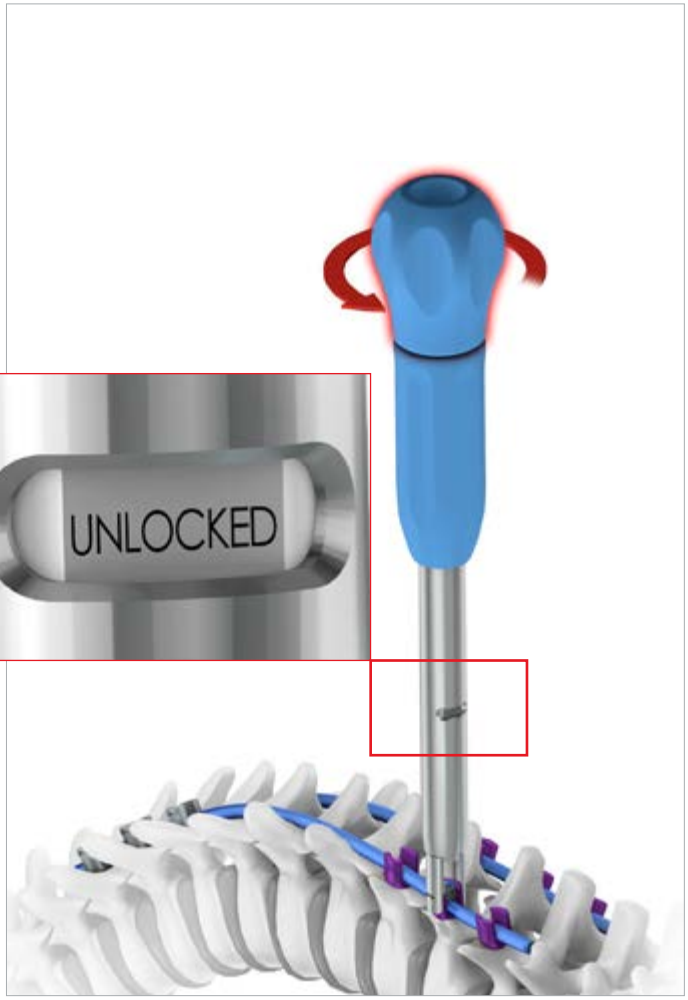
Set the device into the UNLOCKED position, then put it on the head of transpedicular screw, centre it, then push it down until snapping in the cut-outs of the screw.



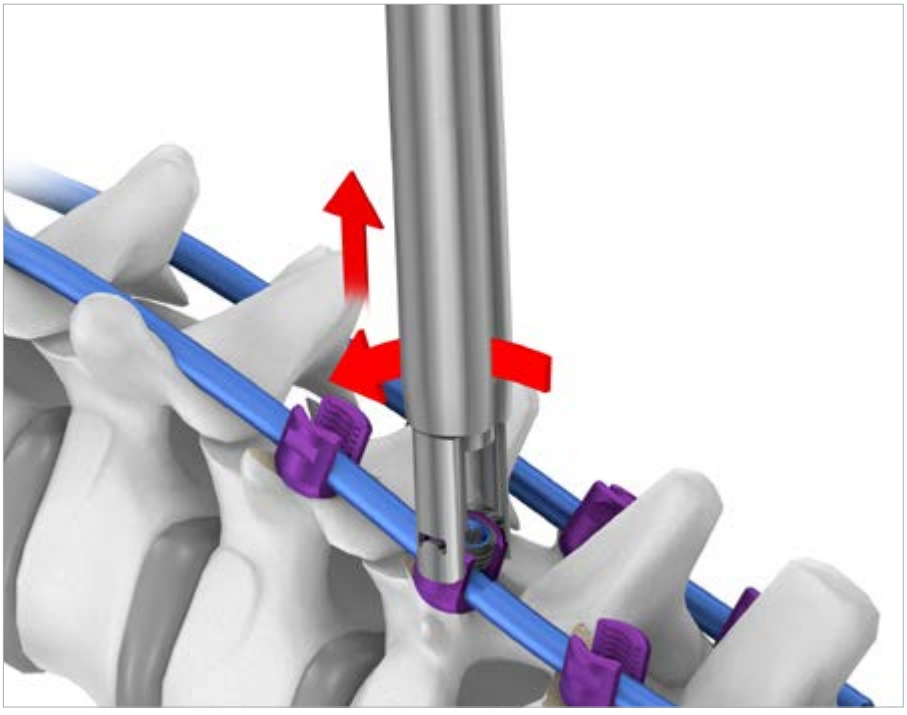
Then, by a turn in a clockwise direction, the rod may be smoothly pushed down to the bottom of the screw.

The rod is completely seated when the elements of the instruments indicate the END position.

To secure the rod, insert the locking screw through the cannulated opening of the screw persuader *(the screw is mounted on the screwdriver tip T30 [40.8111.000])* and initially screw it in.



Then turn the persuader knob in a counterclockwise direction to set the device into the UNLOCKED position.



The device is dismounted from the transpedicular screw by skewing the device in the axis of the rod.

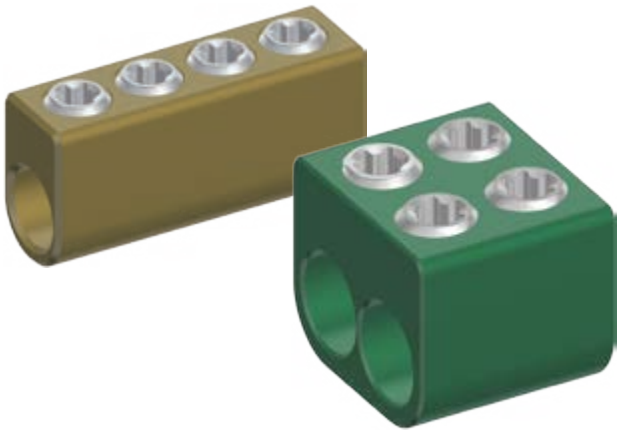
Having established the required vertebrae position, finally screw in the locking screws with the help of T-type torque handle 12Nm **[40.8087.000]** connected with screwdriver tip T30 **[40.8084.000]**.

When the required torque of 12Nm is reached, the dynamometric mechanism signals it with an audible snap.

To eliminate the movement of rod-screws system while screwing in the locking elements use the counter wrench **[40.8095.000]**.

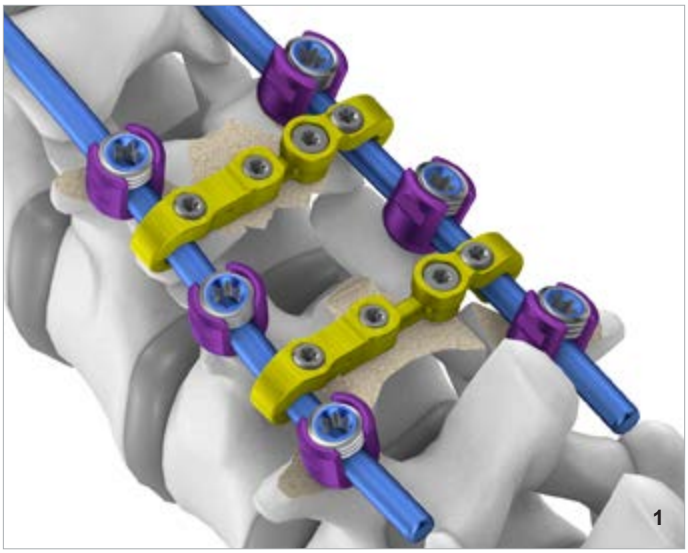
NOTICE:
To maintain high level of safety and correctness of operation of the torque wrench, it is necessary to keep the calibration date presented on the stopper of the instrument handle.
The instrument calibration is performed by the manufacturer - ChM sp. z o.o.

If it is needed to lengthen the fixation in lateral direction *(in relation to the main axis of stabilization)*, it is possible to use a lateral connector. The connector is put on the main rod, then it is locked in a desired position *(after mounting the appropriate transpedicular screw)*.



When it is necessary to use two sections of rods *(e.g. in case of scolioses)*, it is possible to use the following connectors:

- crosswise connector,
- parallel connector.

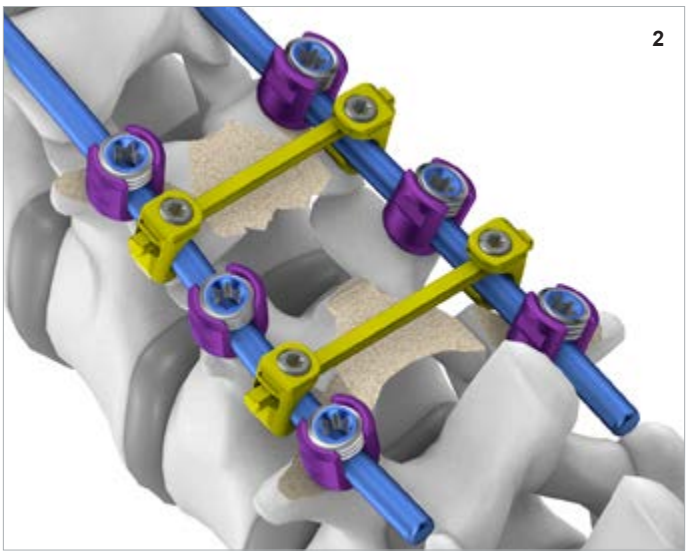


1

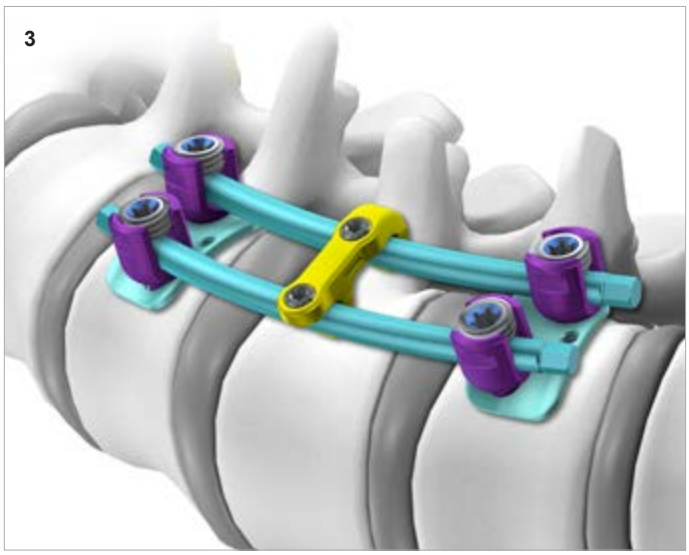
CHARSPINE2 allows for increase of rotational stability of the system by connecting two sides of rods with the help of a crosswise connector.

CHARSPINE2 offers three types of crosswise connectors:

1. regulated crosswise connectors.
2. clamp crosswise connectors with rod connectors.
3. solid crosswise connectors (intended for dual-rod stabilization with an anterior approach.



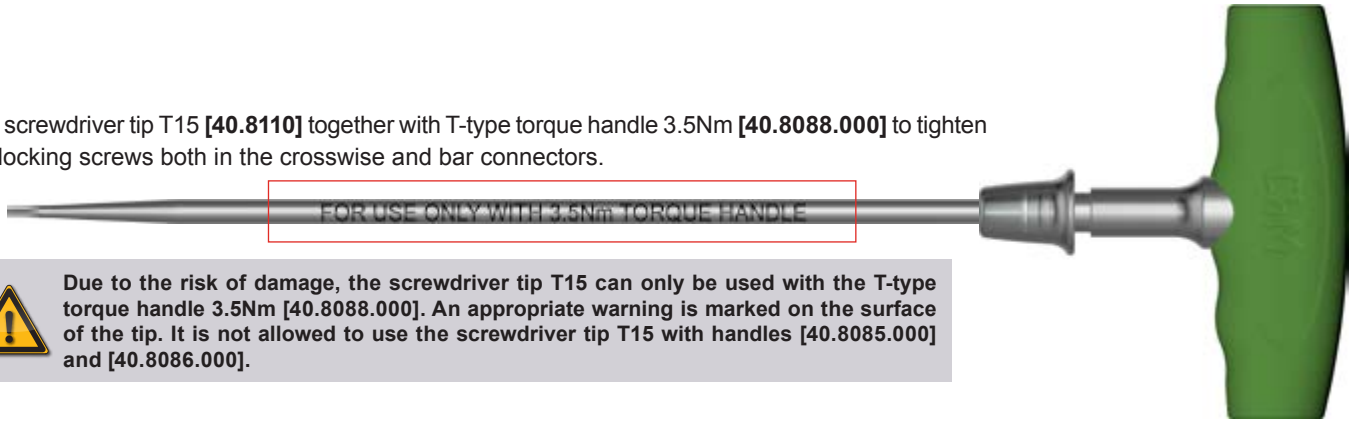
2



3

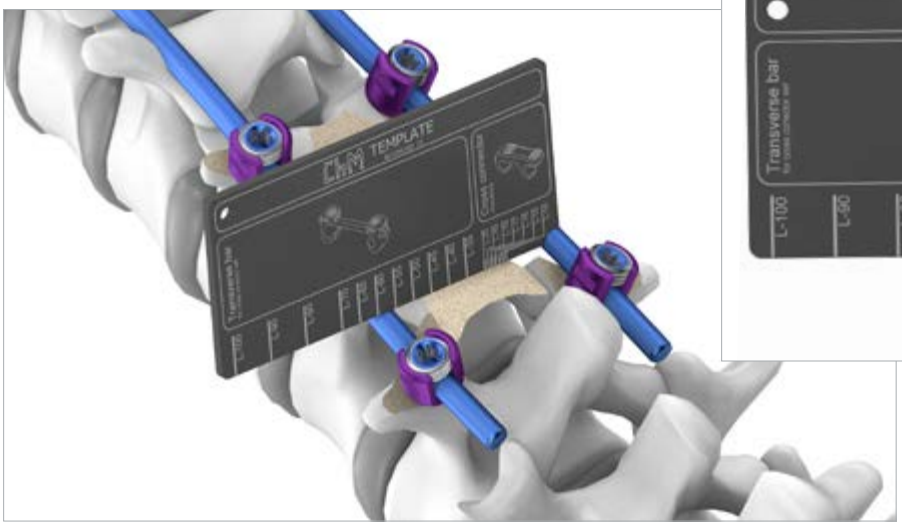
Crosswise connectors are inserted with the use of holder for crosswise connectors **[40.8067.000]**.

Use screwdriver tip T15 **[40.8110]** together with T-type torque handle 3.5Nm **[40.8088.000]** to tighten the locking screws both in the crosswise and bar connectors.



Due to the risk of damage, the screwdriver tip T15 can only be used with the T-type torque handle 3.5Nm [40.8088.000]. An appropriate warning is marked on the surface of the tip. It is not allowed to use the screwdriver tip T15 with handles [40.8085.000] and [40.8086.000].

To facilitate the selection of appropriate length of the crosswise connector, use the template **[40.5248.000]**

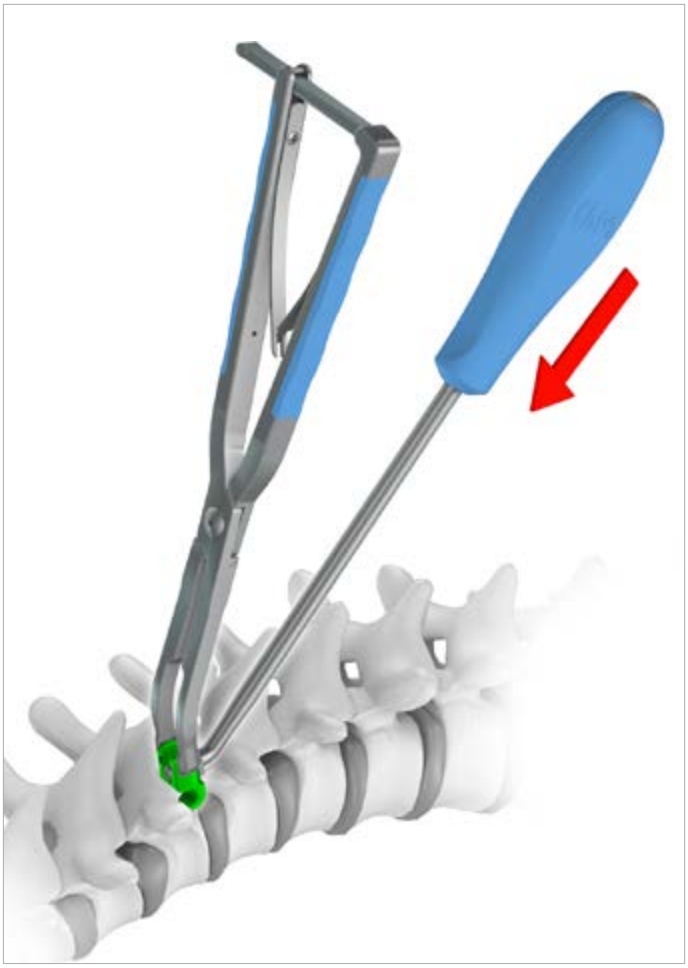


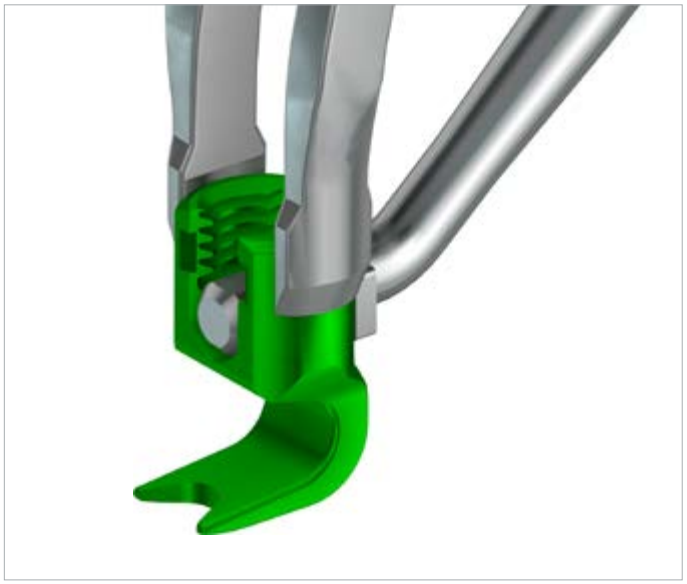
IV.8. HOOKS INSERTION

IV.8.1. PEDICLE HOOKS INSERTION

Pedicle hook is used for fixation of thoracic vertebrae and it is recommended for spine section between T10 and T1 vertebrae. Pedicle hook is always inserted in rostral direction, so its split blade leans on the vertebral arch pedicle.
Place for pedicle hook insertion is prepared by a limited facetectomy. When on the desired level, two incisions are made on the surface of the inferior transverse process, enabling the access to the cartilage of the superior transverse process of the preceding vertebra.

Hook insertion point may be prepared with the use of raspatory for pedicle hooks **[40.8107.000]** by careful insertion in slightly lateral direction *(in relation to the medial line)* until the pedicle is identified. It is vital not to penetrate medially the spine canal.





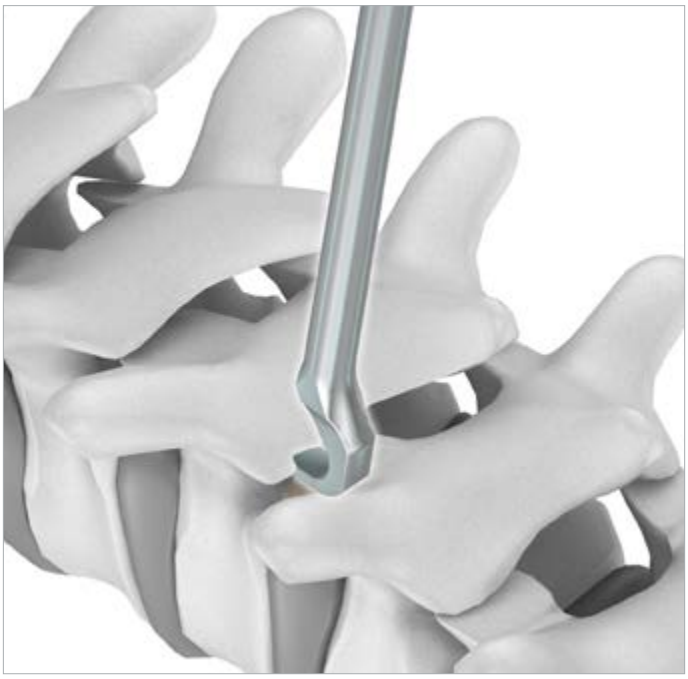
When the place of insertion is ready, the hook is inserted with the help of hook holder **[40.8101.000]**, and then it is carefully impacted to the desired position with the use of impactor for hooks **[40.8103.000]**.

IV.8.2. INSERTION OF LAMINAR HOOKS

Laminar hooks are used in thoracolumbar spine. They may be inserted in rostral or caudal direction, depending on the spine section instrumented. A wide range of laminar hooks is available. The selection of appropriate hooks depends on the anatomy of the insertion point:

- in case of a hook inserted in caudal direction *(supralaminar manner)*, it is recommended to use the thoracic hook with narrow blade to avoid excessive penetration of the spine canal with the hook blade.
- offset laminar hooks are recommended in situations when standard hooks do not ensure collinearity of inserted implants.
- extended laminar hooks are used in situation when a specific height *(in relation to other implants)* has to be maintained.

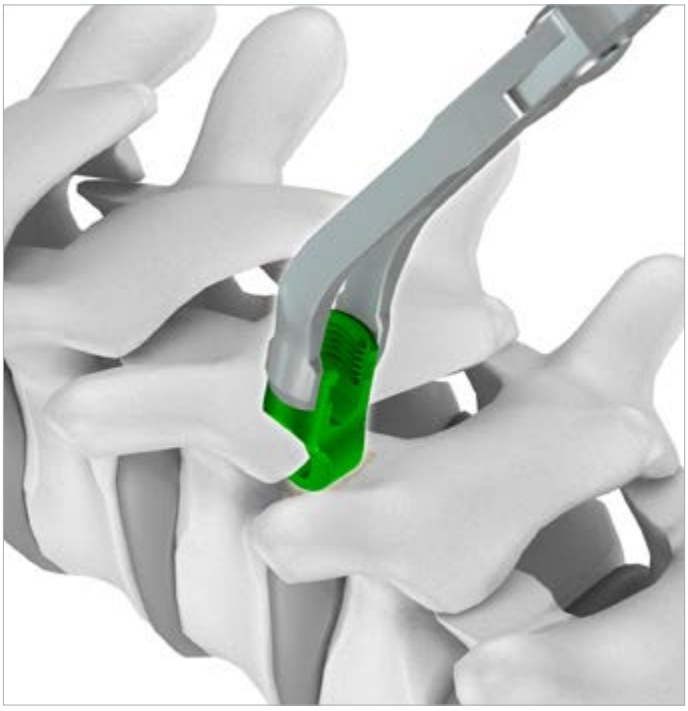
Laminar hook blade is inserted in space above the dura mater. To allow for appropriate passage of hook in spinal canal, a ligamentum flavum is removed and a limited laminectomy is performed.



During the preparation of space for hooks the following raspatories for laminar hooks may be used:

- narrow **[40.8104.000]**,
- standard **[40.8105.000]**,
- wide **[40.8106.000]**.

Blade widths correspond to widths of laminar hooks accessible.

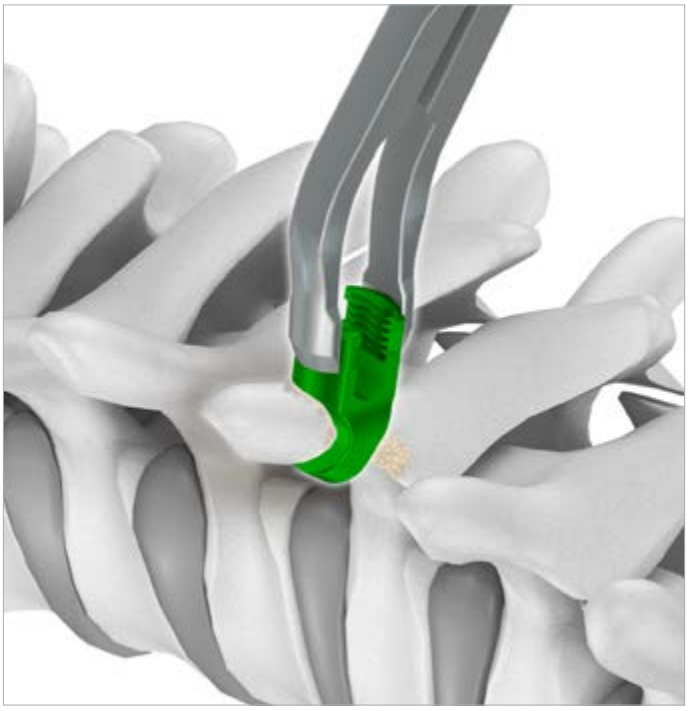


The selected hook is mounted in jaws of a hook holder **[40.8101.000]** and then implanted in a prepared site in vertebral pedicle.

Alternatively, the selected hook may be mounted in jaws of lateral hook holder **[40.8102.000]**, e.g. in situation when anatomical structure hinders the use of a holder **[40.8101.000]**.

IV.8.3. INSERTION OF TRANSVERSE PROCESS HOOKS

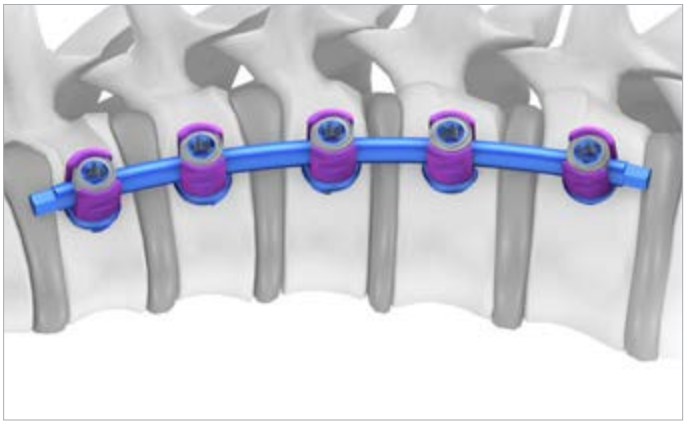
Transverse process hooks are often used in thoracic spine region because of fairly large size of transverse process. Hooks may be inserted in rostral or caudal position. When the hook is inserted on a transverse process in caudal direction, it may be used for insertion *(in one line)* with inferiorly offset pedicle hook to achieve an appropriate fixation and to ensure better stability.
Therefore, between the transverse process and the rib in front of the process, an upper and lower surface of the transverse process is prepared with the use of raspatory for laminar hooks **[40.8105.000]**.



Mount the selected hook on a hook holder **[40.8101.000]** and then insert it on a prepared transverse process.

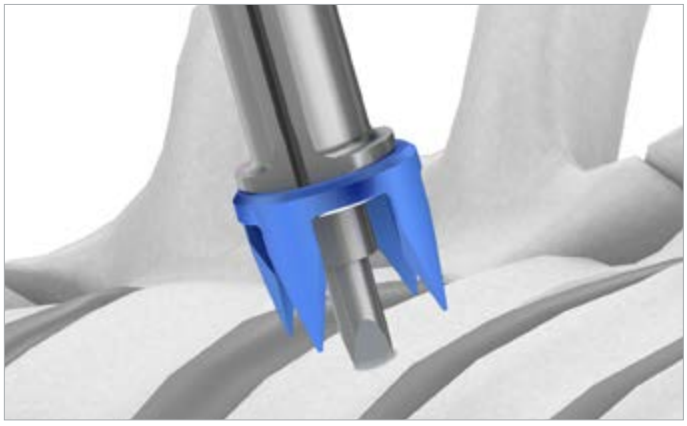
IV.9. INSERTION OF SCREWS - ANTEROLATERAL APPROACH

In general, the anterior approach is used for treatment of single-arch scolioses situated in thoracic or thoracolumbar spine. CHARSPINE2 is designed to ensure single- and dual-rod stabilization with an open method by thoracotomy or thoracolumbar approach *(abdominal)*.

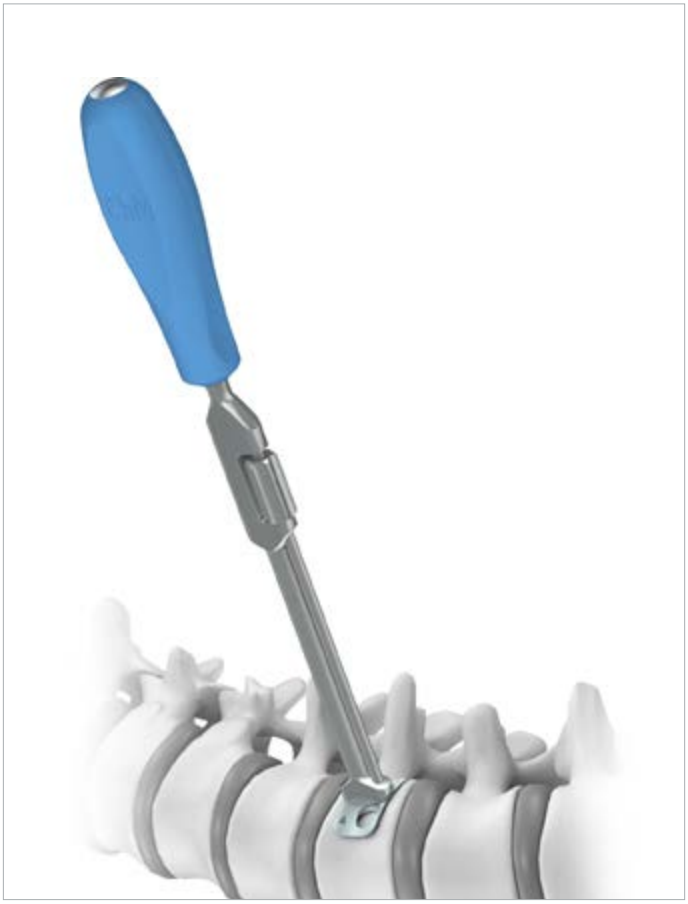


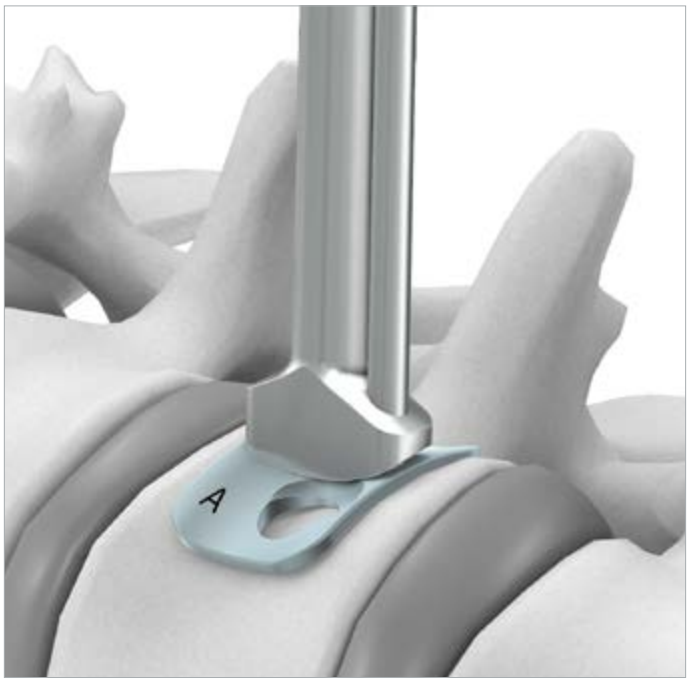
It is recommended to use a dual-rod system because of a higher strength and stability. However, during the treatment of thoracic scolioses the insertion of two screws into each vertebral pedicle may be anatomically difficult, especially in upper and medial thoracic vertebrae. In such case a single-rod stabilization, or a single-rod stabilization for proximal segments and dual-rod stabilization for distal segments may be used.

The implantation begins with the insertion of single- and double-hole staples *(depending on the instrumented spine level)*.
Both single- and double-hole staples evenly distribute the pressure on the surface of vertebrae pedicles and prevent splintering of vertebrae pedicles during corrective manipulation.



Single-hole staples are inserted and positioned with the use of a trocar **[40.8073.000]** with a staple holder **[40.8099.00]** attached.

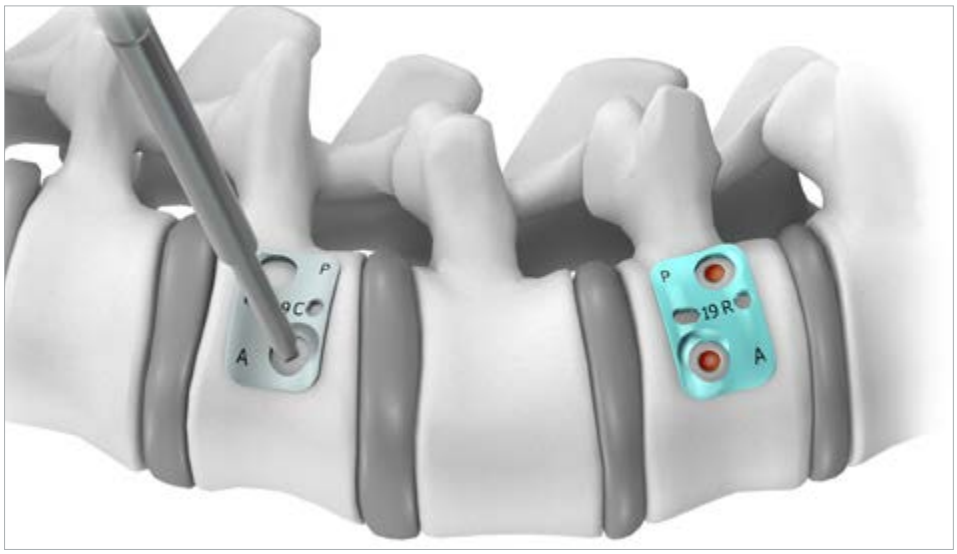




Double-hole staples are inserted and positioned with the help of an impactor for staples **[40.8098.000]**.

If necessary, the staples may be impacted to reach the desired position. Impaction is to be performed with the help of a metal hole plug on the handle of impactor for staples.

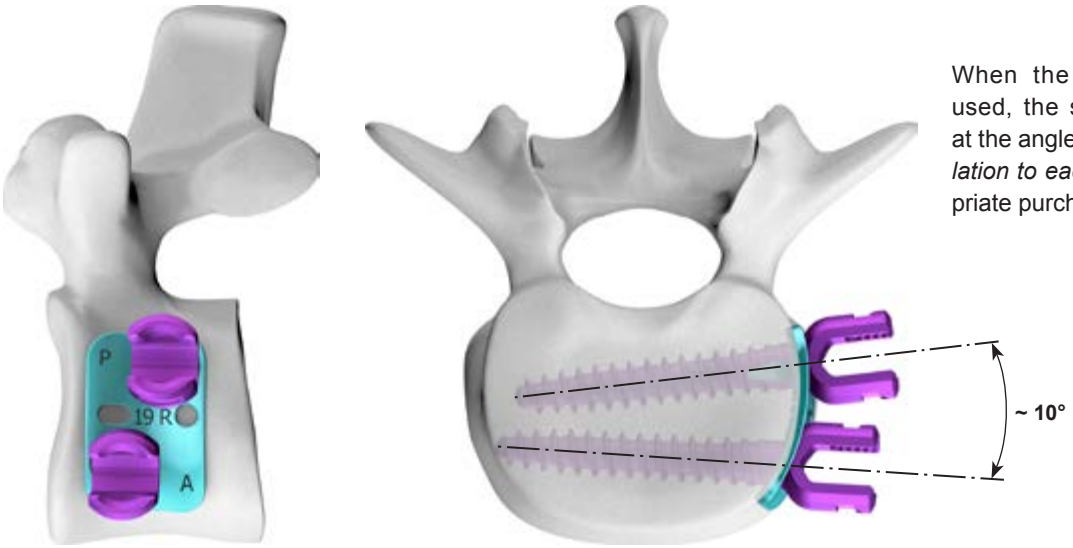
Screw insertion point should be prepared with the help of a trocar **[40.8073.000]** which penetrates the cortex of the vertebral body in the center of the staple hole.



When the spinal column is approached from the left side *(lumbar section)*, the double-hole staples are marked for better understanding: letter R *(for staples oriented rostrally)* and letter C *(for staples oriented caudally)*.

When the right-sided approach is used *(thoracic section)*, the orientation of staples should be reversed: staples with letter R should be oriented caudally, while staples with C - rostrally.

In addition, the staples are marked with letters A *(ANTERIOR)* and P *(POSTERIOR)* to allow establishing the correct staples positioning during the insertion.



When the double-hole staples are used, the screws should be inserted at the angle of approximately 10° *(in relation to each other)* to allow for appropriate purchase in the bone.

NOTICE:
To avoid any screw penetration in direction of the spine canal the staple should not be inserted too far into the anterior direction.

The insertion and locking of screws is performed in the same manner as already described in chapter INSERTION OF SCREWS - ANTERIOR APPROACH

IV.10. IMPLANT REMOVAL

To perform revision, the following steps should be taken *(observing the order provided)*.

1. Use the screwdriver T30 **[40.8111.000]** to loosen and remove the locking screws.
2. Use the pliers for rod **[40.8109.000]** to remove the rods.
3. Remove the anchoring implants *(transpedicular screws or hooks)*. Depending on the implant inserted use either the wrench for monoaxial screws **[40.8089.000]**, wrench for polyaxial screws **[40.8090.000]** or hook holder **[40.8101.000]**.

GB

ISO 9001/ ISO 13485

CE

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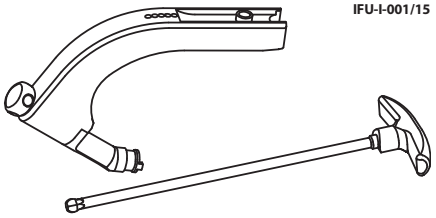
IFU-I-001/15



GB

INSTRUCTIONS FOR USE REUSABLE ORTHOPAEDIC AND SURGICAL INSTRUMENTS

DESCRIPTION AND INDICATIONS

Instruments manufactured by **ChM** sp. z o.o. are mainly made of steel, aluminium alloys and plastics used in medicine and in accordance with the applicable procedures.

Each medical instrument is exposed tooccurrence of corrosion, stains and damage if not treated with special care and according to recommendations provided below.

The use of instruments in accordance with their intended purpose prolongs their usability.

Instrument's durability is limited and highly related to the manner and frequency of its usage.

The unit package contains one piece of the product in non-sterile condition. The welded clear foil sleeve is typical packaging material. The products may also be supplied as complete sets *(arranged on trays and placed into specially designed sterilization containers)*.

This Instructions For Use is attached both to the unit package and to the instrument set as well.

The packaging is equipped with the product label. The label contains:
- **ChM** logo and the manufacturer's address,
- name, size and catalogue number of the device *(REF)*, e.g.: 40.XXXX.XXX,
- production batch number *(LOT)*, e.g.: XXXXXXX,
- NON-STERILE sign: indicates non-sterile product,
- information symbols *(described in the footer of this Instructions For Use)*.

Depending on the size or type of the product, the following information may be marked on its surface: **ChM** logo, production batch no. *(LOT)*, catalogue no. *(REF)*, type of material and device size.

MATERIALS

Devices are produced of corrosion-resistant steel. The protective layer *(passive layer)* against corrosion is formed on the surface of the steel due to high content of chromium.

Devices produced of aluminium are mainly stands, palettes, cuvettes and some parts of instruments such as handles of screwdrivers, awls or wrenches, etc. The protective oxide layer, which may be dyed or stays in natural colour *(silvery-grey)*, is formed on the aluminium as an effect of electrochemical treatment on its surface.

Devices made of aluminium with processed layer have a good corrosion resistance.

The contact with strong alkaline cleaning and disinfecting agents, solutions containing iodine or some metal salts, due to chemical interference with the processed aluminium surface, shall be avoided.

Devices are mainly manufactured out of the following plastics: PPSU *(Polyphenylsulfone)*, PEEK *(Polyetheretherketone)* and teflon *(PTFE - Polytetrafluoroethylene)*.

The above mentioned materials can be processed *(washed, cleaned, sterilized)* at temperatures not higher than 140°C, they are stable in aqueous solution of washing-disinfecting agents with pH values from 4 to 10.8.

If the material of the device cannot be specified, please contact ChM sp. z o.o. representative.

WARNINGS AND PRECAUTIONS

1. Reusable orthopaedic and surgical instruments are intended for use in operating room conditions only by skilled and trained medical professionals, specialists in surgery, who are familiar with their use and application.
2. The surgeon should be familiar with all components of the device before use and should personally verify if all components and devices are present before the surgery begins.
3. Prior to the device usage and before procedure begins, all components of instruments should be carefully inspected for proper functioning and condition.Blades of all cutting edges should be sharp and undamaged. Replace any damaged accessory immediately. Employing bent or damaged surgical instruments in surgery is not allowed.
4. Tissue structures close tooperative site must be protected.
5. Contact of the instrument with metal operating equipment, retractors or other devices may cause damage that necessitates intraoperative replacement of that instrument.
6. Do not apply excessive force when using the instrument – it may lead to its faulty operation and, in consequences, to permanent damage.
7. While rare, intraoperative fracture or breakage of the instrument can occur. Instruments which have been subjected to extensive use or extensive force are more susceptible to fractures, depending on care taken during surgery and the number of procedures performed.
8. In the case of breakage and presence of instrument fragments in the patients' body, remove and dispose of them following the appropriate protocol of the unit.
9. In the case of suspected or documented allergy or intolerance to metallic materials, surgeon shall find out if the patient develops allergic reaction to the instrument material by ordering appropriate tests.
10. Improper or careless handling of the instruments and related chemical, electrochemical and physical damage may adversely affect the corrosion resistance and shorten the life of the instruments.
11. Reusable orthopaedic and surgical instruments are intended only for specific procedures and must be used strictly according to their intended purpose. Use of instruments not in accordance with their intended purpose may lead to malfunction, accelerated wear and – in consequences – damage of the instrument.
12. It is extremely important to follow the calibration deadline which is permanently marked on the torque instruments *(see CALIBRATION)*. Use of a torque instrument with an overstepped calibration date may lead to potential injury, implant or device damage, or loss of correction.

If there appear any irregularities in device operation, e.g. due to heavy usage, prior to next calibration date, the instrument should be immediately sent to the manufacturer for its re-calibration.

CLEANING, DISINFECTION AND STERILIZATION

Prior to use of a non-sterile device the following rules apply:

- Before use, the device must undergo cleaning, disinfection and sterilization procedures. It is recommended to use an automated procedure *(washer-disinfector)* for cleaning and disinfecting.
- Effective cleaning is a complicated procedure depending on the following factors: the quality of water, the type and the quantity of used detergent, the techniques of cleaning *(manual, ultrasound, with the use of washing/disinfecting machine)*, the proper rinsing and drying, the proper preparation of the instrument, the time, the temperature and carefulness of the person conducting this process.

Preparation for cleaning

After removing the product from its original packaging and before each cleaning, remove possible surface contamination using a disposable cloth, paper towel or plastic brushes *(nylon brushes are recommended)*.

It is not permitted to use brushes made of metal, bristles or materials which can cause damage to the device.

Cleaning and disinfection process

Chosen detergents and disinfectants must be suitable and approved for use with medical devices. It is important to follow the instructions and restrictions specified by the producer of these detergents.

CAUTION:

To avoid product damage (pitting, rust), **DO NOT** *use highly aggressive agents (NaOH, NaOCl), salt solutions and other unsuitable cleaning agents. It is recommended to use aqueous solutions of washing-disinfecting agents with a pH value between 7 and 10.8.*

Manual cleaning

- Apply cleaning agent solution to the product surfaces with careful brushing. A suitable brush must be used for cleaning holes.
- If applicable, ultrasonic cleaning may be used. The ultrasonic bath must be prepared according to the manufacturer's instructions.
- Next rinse thoroughly under running water. It is recommended to use demineralized water.
- Visually inspect the entire surface of the device for damage and contaminants. Damaged products must be removed. For contaminated products, the cleaning process should be repeated.

CAUTION:

- *Never use metal brushes, files or sponges for contaminants removal.*
- *Rinse thoroughly and carefully. Sterile demineralized water facilitates water spots removal from the instrument's surface.*
- *Instruments with cannula should be blown through using compressed air gun, or air supplied from a syringe.*
- *If the accumulated in the cannula material cannot be removed in accordance with the instructions, the device should be considered at the end of its useful life and should be disposed of in accordance with the facility procedures and guidelines.*

Cleaning with washer-disinfector

The device should undergo a process of machine washing in the washer-disinfector *(use washing-disinfecting agents recommended for medical devices)*.

CAUTION: The cleaning/disinfecting appliances should be compliant with requirements specified in ISO 15883.

Procedure of washing in the washer-disinfector shall be performed according to internal hospital procedures, recommendations of the washing machine manufacturer, and instructions for use prepared by the washing-disinfecting agents manufacturer.

Disinfection should be carried out at 90° *(soak for at least 10 minutes in demineralized water)* without the use of detergents.

Drying

Drying of the device must be performed as a part of the cleaning/ disinfection process.

Inspection

Before preparing for sterilization, all medical devices should be inspected.

Generally, visual inspection under good light conditions is sufficient. All parts of the devices should be checked for visible soil and/or corrosion. Particular attention should be paid to:

- soil traps such as mating surfaces, hinges, recesses, instruments shafts,
- holes, cannulations,
- places where soil may be pressed during use,
- cutting edges should be checked for sharpness and damage,
- special care should be taken to inspect the instruments for complete dryness prior to their storage.

Functional checks should be performed where possible:

- mating devices should be checked for proper assembly,
- all reusable orthopaedic and surgical instruments should be checked for straightness.

CAUTION:

The **ChM** *sp. z o.o. does not define the maximum number of uses appropriate for re-usable medical instruments. The life of these devices depends on many factors including the method, way and duration of each use, and the handling between uses.*

Inspection and functional testing of the device must be carried out before each use. In the case of identified damage, the instrument must not be used again.

ATTENTION! The manufacturer does not recommend using any preservatives on surgical and orthopedic devices.

Packaging

The product supplied non-sterile must be repacked in a packaging intended for a specific sterilization method that meets the requirements of ISO 11607-1 and is marked with CE sign. The packaging procedure must be performed in controlled purity conditions. The product must be packed in such a way that during removal from the package to be used, there is no risk for its contamination. Sterilization package is designed to maintain the sterility of medical devices after the sterilization process and during their storage prior to use.

Sterilization

Before each sterilization procedure and application, the device has to be controlled. The device is to be efficient, without toxic compounds like residues after disinfection and sterilization processes and without structure damage *(cracks, fractures, bending, peeling)*. Remember that sterilization is not a substitute for cleaning process!

Disinfected, washed, and dried device shall undergo the sterilization process in accordance with the client procedures. The recommended method of sterilization is vacuum-type steam sterilization *(with water vapor under overpressure)*:

- temperature: 134°C,
- minimum exposure time: 7 min,
- minimum drying time: 20 min.

CAUTION:

- *Sterilization must be effective and in accordance with requirements of the EN 556 standard which means that theoretical probability of presence of a living microorganism is less than 1/10⁶ (SAL=10⁻⁶, where SAL stands for Sterility Assurance Level).*
- *Device must not be sterilized in the package in which it was delivered, except specially designed sterilization containers.*
- *Validated sterilization methods are allowed.*
- *Sterilization of surgical instruments shall be carried out using appropriate equipment and under the conditions that conform to applicable standards.*
- *Devices manufactured out of plastics (PPSU, PEEK, PTFE) may be sterilized by any other available sterilization method validated in the centre but the sterilization temperature is not to be higher than 140°C.*

Durability and strength of instruments to a considerable degree depend on how they are used. Careful usage consistent with intended use of the product protects it against damage and prolongs its life.

STORAGE

The devices should be properly stored. When storing surgical instruments it is recommended that they never be stacked together. It may lead to damage of cutting edges *(nick or dull)* and/or initiation of corrosion centers. Instruments should be stored in dark, dry room, if possible – in suitable storage racks and placed into specially designed sterilization containers.

CALIBRATION

1. Regular calibration is required in case of torque wrenches, handles and connectors. Torque instruments are factory-calibrated, the nominal torque of a calibrated instrument is marked on the device *(e.g. 4 Nm)*.

   To maintain a high level of safety and accuracy of operation of a torque instrument, it is necessary to follow the calibration deadline which is marked on the device.
2. The calibration is conducted by the manufacturer – **ChM** sp. z o.o. Any unauthorized modifications of the structure or default, factory settings may lead to potential injury or device damage and are forbidden.

If this instructions appears unclear, please contact the manufacturer, who shall provide all required explanations.

Updated INSTRUCTIONS FOR USE are available on the following website: **www.chm.eu**

IFU-I-001/15; Date of verification: December 2015

SYMBOL TRANSLATION • OBJAŠNIENIA SYMBOLI • ПОЯСНЕНИЕ ОБОЗНАЧЕНИЙ • EXPLICACIÓN DE LOS SÍMBOLOS • SYMBOLERKLÄRUNG • SYMBOLY PŘEKLADY • TRADUZIONE SIMBOLI

	Do not reuse • Nie używać powtórnie • Не использовать повторно • No reutilizar • Nicht wiederverwenden • Nepoužívejte opakovaně • Non riutilizzare
	Do not resterilize • Nie sterylizować ponownie • Не стерилизовать повторно • No reesterilizar • Nicht resterilisieren • Nepoužívejte resterilizaci • Non risterilizzare
	Do not use if package is damaged • Nie używać jeśli opakowanie jest uszkodzone • Не использовать при поврежденной упаковке • No utilizar si el envase está dañado • Nicht verwenden falls Verpackung beschädigt ist • Nepoužívejte, pokud je obal poškozen • Non utilizzare se la confezione è danneggiata
	Consult Instructions for Use • Zajrzyj do instrukcji używania • Обратитесь к инструкции по применению • Consultar instrucciones de uso • Siehe die Gebrauchsanweisung • Řiďte se návodem k použití • Consultare le instruzioni per l'uso
NON STERILE	Non-sterile • Niesterylny • Не стерильно • No estéril • Unsteril • Nesterilní • Non sterile
	Caution • Ostrzeżenie • Осторожно • Advertencia • Vorsicht • Varování • Attenzione leggere il foglietto illustrativo
STERILE R	Sterilized using irradiation • Sterylizowany przez napromieniowanie • Радиационная стерилизация • Esterilizado mediante radiación • Sterilisiert durch Bestrahlung • Sterilizovat zářením • Sterilizzato mediante irradiazione
STERILE VH202	Sterilized using hydrogen peroxide • Sterylizowany nadtlenkiem wodoru • Стерилизован перекисью водорода • Esterilizado con peróxido de hidrógeno • Sterilisiert mit Wasserstoffperoxid • Sterilizováno s peroxidem vodíku • Sterilizzato mediante perossido di idrogeno
REF	Catalogue number • Numer katalogowy • Номер по каталогу • Número de catálogo • Katalognummer • Katalogové číslo • Numero di catalogo
LOT	Batch code • Kod partii • Код партии • Código de lote • Chargennummer • Číslo šarže • Codice del lotto
Mat:	Material • Materiał • Материал • Material • Materiál • Materiál • Materiale
Qty:	Quantity • Ilość • Количество • Cantidad • Menge • Množství • Quantita'
	Use by • Użyć do • Использовать до • Usar antes de • Verwenden bis • Použijte do • Da utilizzare entro il

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CE 0197
ISO 9001
ISO 13485