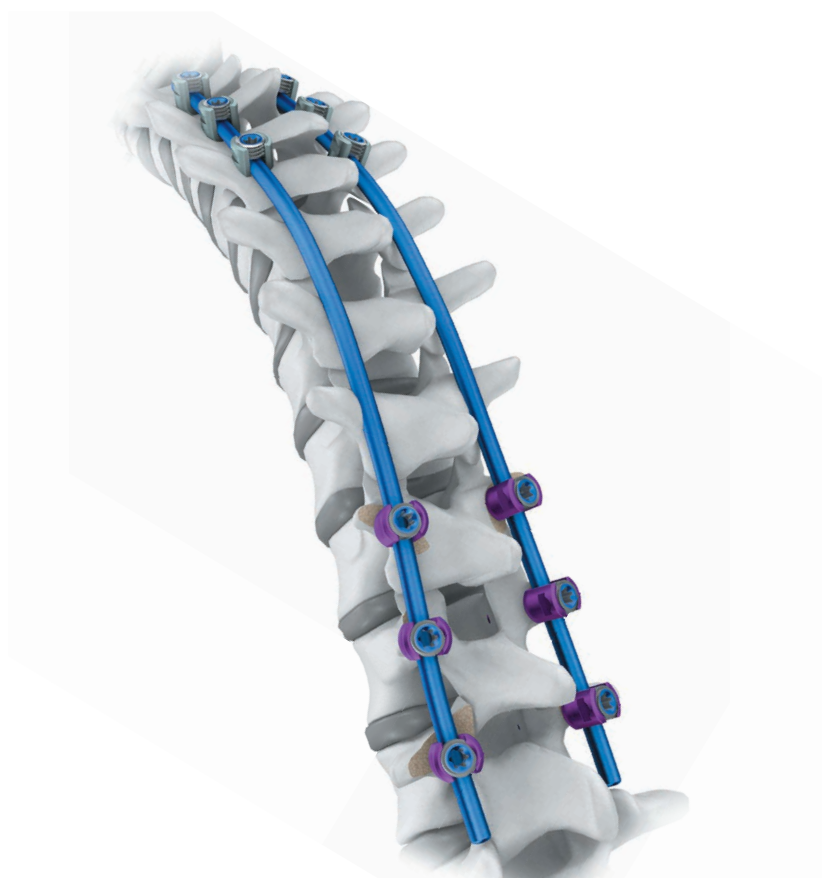


CHM[®]

CHARSPINE *system 2*

SPINE STABILIZATION

- *IMPLANTS*
- *INSTRUMENT SET 15.0907.001*
- *INSTRUMENT SET 15.0907.002*
- *ADDITIONAL INSTRUMENTS*
- *SURGICAL TECHNIQUE*



SYMBOLS DESCRIPTIONS



Caution - pay attention to the particular proceeding.



Perform the activity with X-Ray control.



Information about the next stages of the proceeding.



Proceed to the next stage.



Return to the specified stage and repeat the activity.



Before using the product, carefully read the Instructions for Use supplied with the product. It contains, among others, indications, contraindications, side effects, recommendations and warnings related to the use of the product.



The above description is not a detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

www.chm.eu

Document No ST/63B

Date of issue 02.08.2017

Review date P-010-19.02.2019

The manufacturer reserves the right to introduce design changes.

I. INTRODUCTION	5
II. IMPLANTS	8
III. INSTRUMENTS	32
III.1. CONTAINERS ARRANGEMENT	39
IV. SURGICAL TECHNIQUE	42
IV.1. THORACOTOMY	42
IV.2. ANTERIOR THORACOLUMBAR APPROACH	43
IV.3. ANTERIOR RETROPERITONEAL APPROACH	43
IV.4. POSTERIOR APPROACH TO THE THORACOLUMBAR APPROACH	44
IV.5. APPROACH TO POSTERIOR SUPERIOR ILIAC SPINE	44
IV.6. SCREW SELECTION. PREPARATION OF THE SCREW ENTRY POINT	45
IV.7. INSERTION OF SCREWS. POSTERIOR APPROACH	46
IV.8. INTRODUCTION OF POLYAXIAL SCREWS INTO THE PELVIS	63
IV.9. HOOKS INSERTION	65
IV.10. INSERTION OF SCREWS - ANTEROLATERAL APPROACH	68
IV.11. IMPLANT REMOVAL	71

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, hypersensitivity 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.

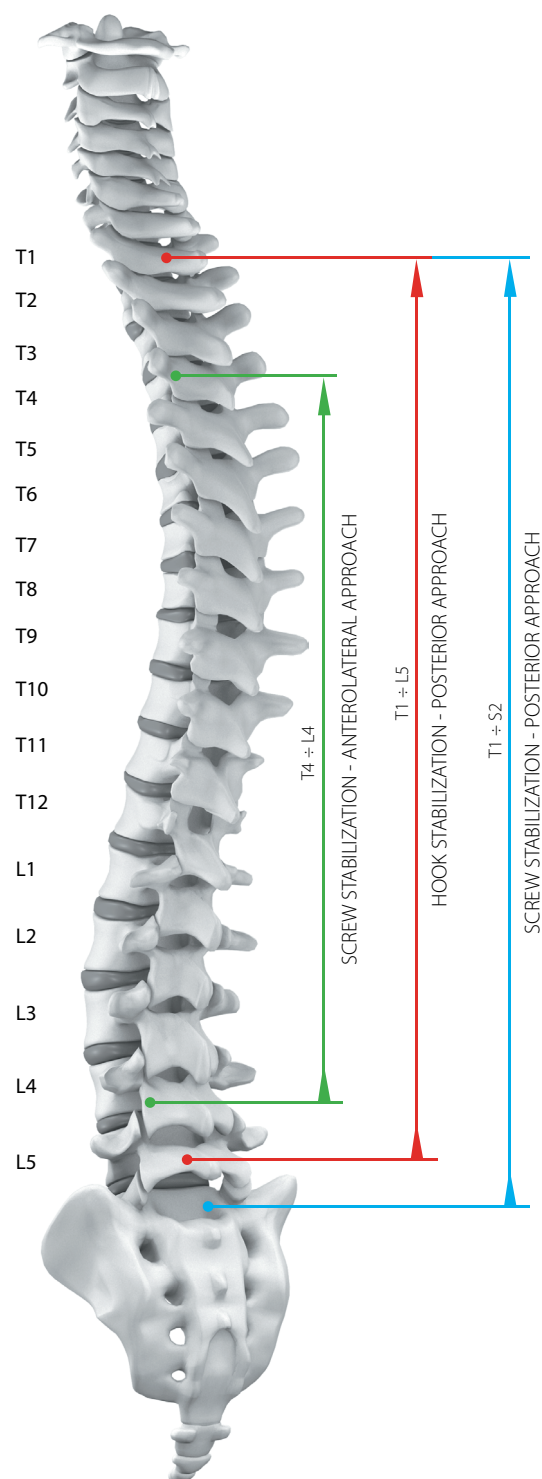
Safety and effectiveness of these systems for any other conditions are unknown.

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 post-operative 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.



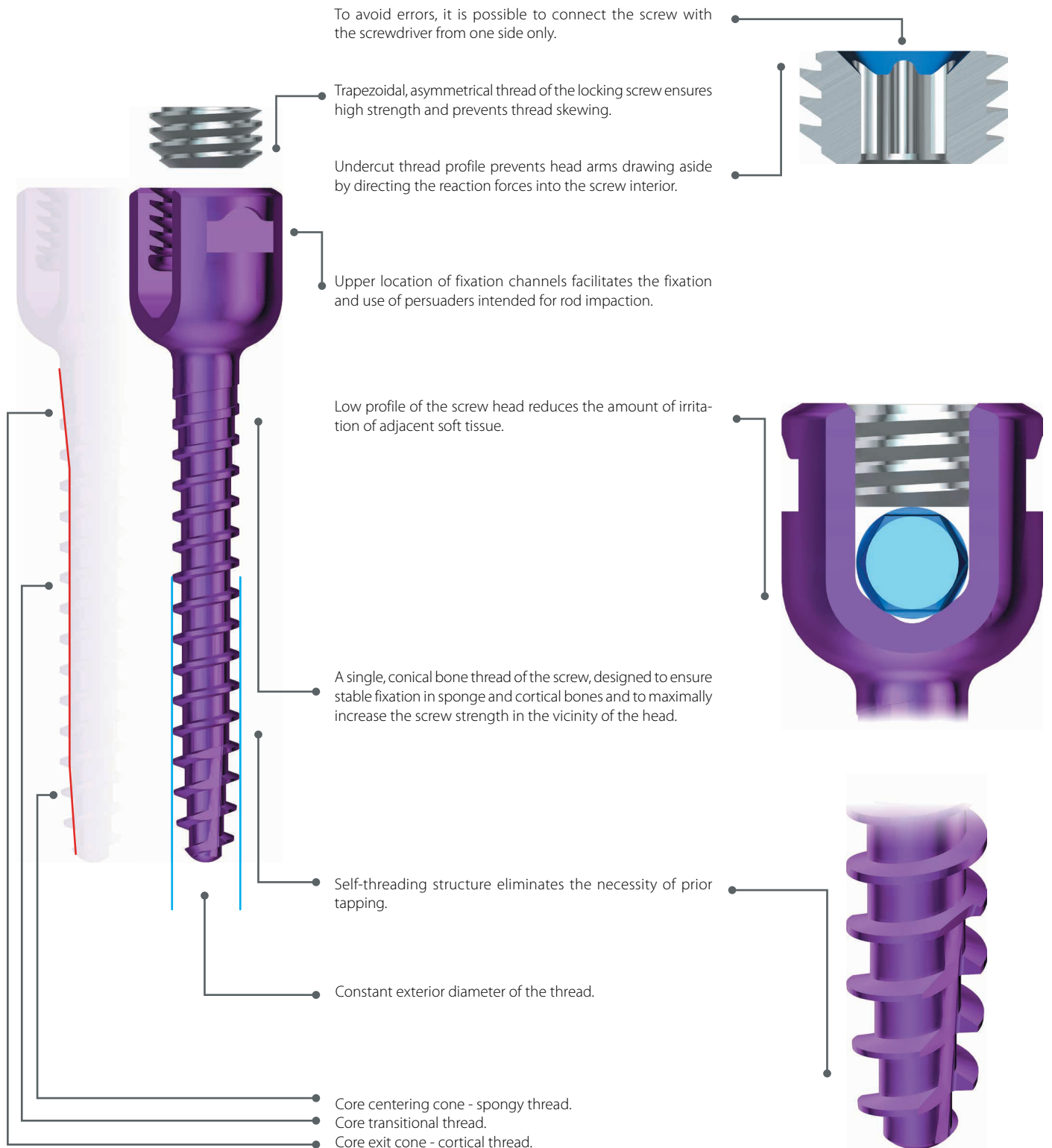


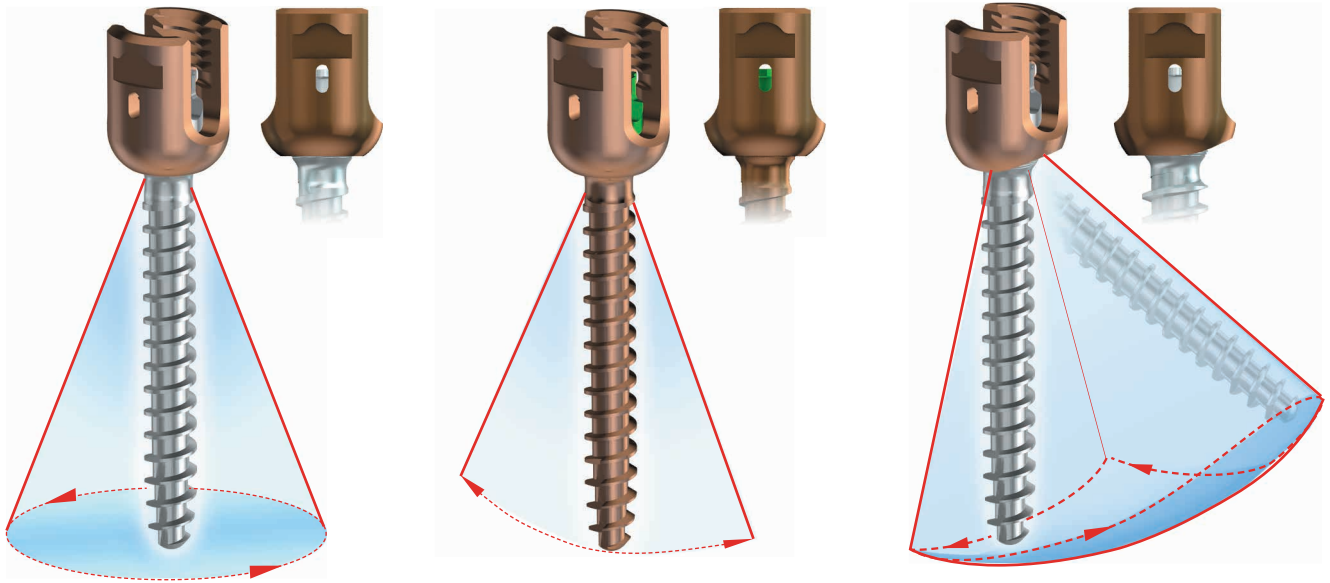
Implants from the **ChM CHARSPINE2** spine stabilization system are designed and tested to be used only with the appropriate **ChM** instrument set. This surgical technique is intended as a guide only. As with any surgical procedure, the surgeon should be thoroughly trained before the procedure and must 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 and the requirements of Directive 93/42/EEC concerning medical devices guarantee high quality of the offered implants.





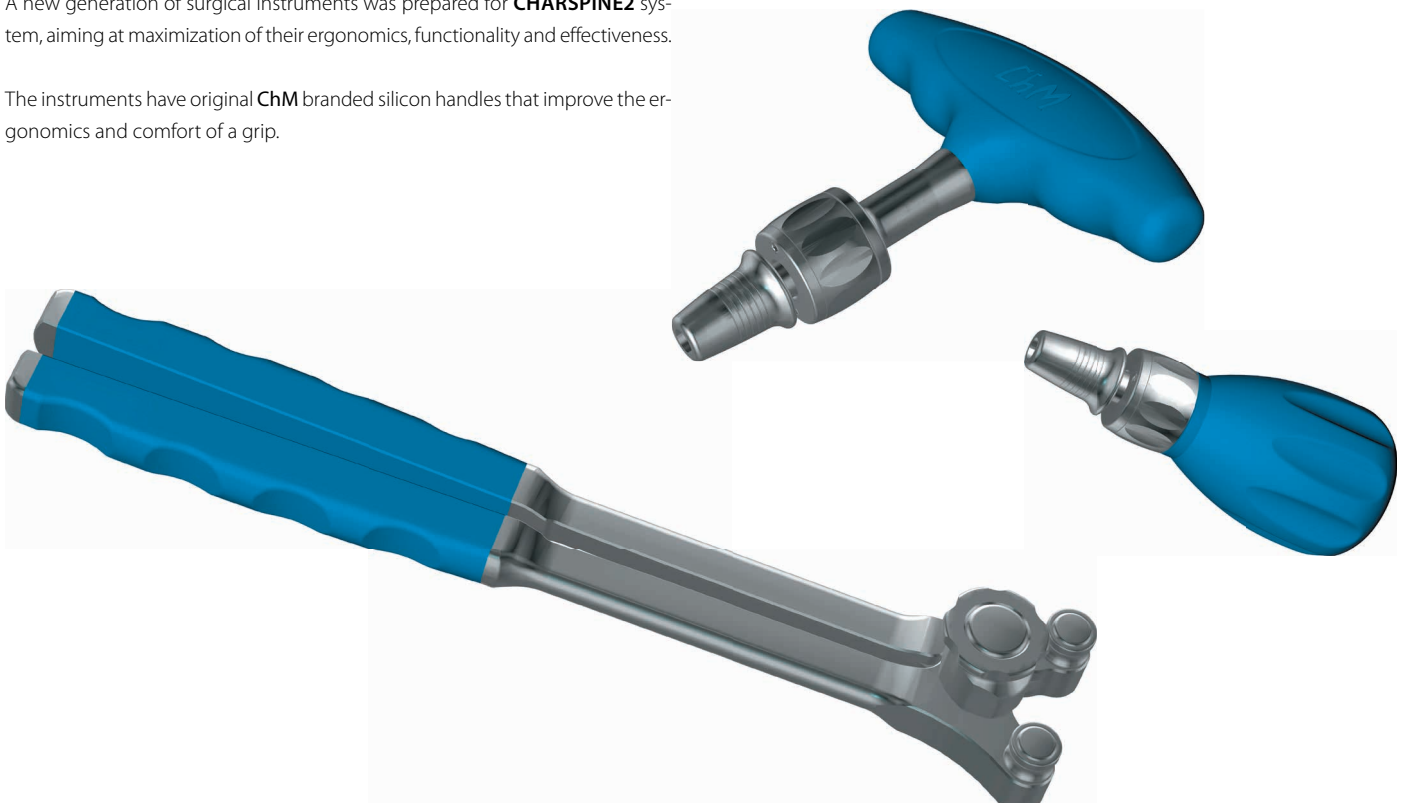
Polyaxial screws allow for stable angular fixation of the screw head in each direction.

Uniplanar screws combine the features of medial-lateral stiffness of monoaxial screws with the mobility of polyaxial screws in the rostral-caudal direction.

Polyaxial screws for pelvis allow for the extension of thoracolumbar spine stabilization and fixation in the pelvic bone. The screws offer an increased asymmetrical range of motion in one of the planes, facilitating the rod-to-screw fixation.

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

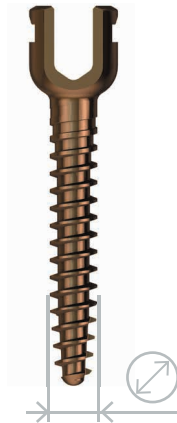
The instruments have original **ChM** branded silicon handles that improve the ergonomics and comfort of a grip.



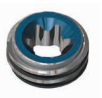
II. IMPLANTS

CHARSPINE2 MONOAXIAL SCREW

CHARSPINE *system 2*



CHARSPINE2 LOCKING SCREW



Ti



3.6160.000



Ø4 Ø4.5 Ø5 Ø5.5 Ø6 Ø6.5 Ø7.5 Ø8.5 Ø9.5 Ø10.5

Colors



	Len	Ti		Len	Ti
4	25	3.6150.125	8.5	25	3.6157.125
	30	3.6150.130		30	3.6157.130
	35	3.6150.135		35	3.6157.135
	40	3.6150.140		40	3.6157.140
	45	3.6150.145		45	3.6157.145
4.5	25	3.6151.125	9.5	50	3.6157.150
	30	3.6151.130		55	3.6157.155
	35	3.6151.135		60	3.6157.160
	40	3.6151.140		65	3.6157.165
	45	3.6151.145		70	3.6157.170
5	25	3.6152.125	10.5	75	3.6157.175
	30	3.6152.130		80	3.6157.180
	35	3.6152.135		85	3.6157.185
	40	3.6152.140		90	3.6157.190
	45	3.6152.145		95	3.6157.195
5.5	50	3.6152.150	10.5	100	3.6157.001
	25	3.6153.125		25	3.6158.125
	30	3.6153.130		30	3.6158.130
	35	3.6153.135		35	3.6158.135
	40	3.6153.140		40	3.6158.140
6	45	3.6153.145	10.5	45	3.6158.145
	50	3.6153.150		50	3.6158.150
	55	3.6153.155		55	3.6158.155
	25	3.6154.125		60	3.6158.160
	30	3.6154.130		65	3.6158.165
6.5	35	3.6154.135	10.5	70	3.6158.170
	40	3.6154.140		75	3.6158.175
	45	3.6154.145		80	3.6158.180
	50	3.6154.150		85	3.6158.185
	55	3.6154.155		90	3.6158.190
7	60	3.6154.160	10.5	95	3.6158.195
	65	3.6154.165		100	3.6158.001
	25	3.6155.125		25	3.6159.125
	30	3.6155.130		30	3.6159.130
	35	3.6155.135		35	3.6159.135
7.5	40	3.6155.140	10.5	40	3.6159.140
	45	3.6155.145		45	3.6159.145
	50	3.6155.150		50	3.6159.150
	55	3.6155.155		55	3.6159.155
	60	3.6155.160		60	3.6159.160
8	65	3.6155.165	10.5	65	3.6159.165
	25	3.6156.125		70	3.6159.170
	30	3.6156.130		75	3.6159.175
	35	3.6156.135		80	3.6159.180
	40	3.6156.140		85	3.6159.185
8.5	45	3.6156.145	10.5	90	3.6159.190
	50	3.6156.150		95	3.6159.195
	55	3.6156.155		100	3.6159.001
	60	3.6156.160			
	65	3.6156.165			
9	70	3.6156.170			
	75	3.6156.175			
	80	3.6156.180			
	85	3.6156.185			
	90	3.6156.190			

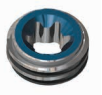
CHARSPINE2 MONOAXIAL REDUCTION SCREW

CHARSPINE *system 2*

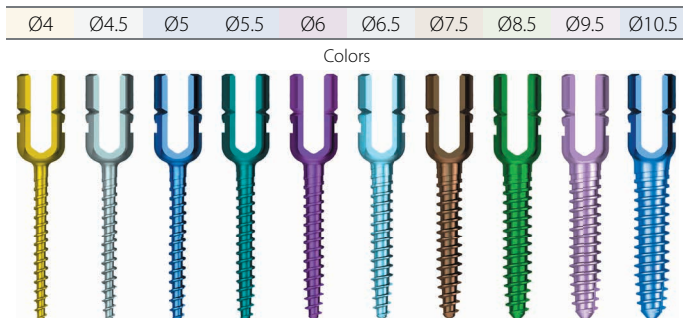


	Len	Ti		Len	Ti
4	25	3.6161.125	8.5	25	3.6168.125
	30	3.6161.130		30	3.6168.130
	35	3.6161.135		35	3.6168.135
	40	3.6161.140		40	3.6168.140
	45	3.6161.145		45	3.6168.145
4.5	25	3.6162.125	9.5	50	3.6168.150
	30	3.6162.130		55	3.6168.155
	35	3.6162.135		60	3.6168.160
	40	3.6162.140		65	3.6168.165
	45	3.6162.145		70	3.6168.170
5	25	3.6163.125	10.5	75	3.6168.175
	30	3.6163.130		80	3.6168.180
	35	3.6163.135		85	3.6168.185
	40	3.6163.140		90	3.6168.190
	45	3.6163.145		95	3.6168.195
5.5	50	3.6163.150	11.5	100	3.6168.001
	25	3.6164.125		25	3.6169.125
	30	3.6164.130		30	3.6169.130
	35	3.6164.135		35	3.6169.135
	40	3.6164.140		40	3.6169.140
6	45	3.6164.145	12.5	45	3.6169.145
	50	3.6164.150		50	3.6169.150
	55	3.6164.155		55	3.6169.155
	25	3.6165.125		60	3.6169.160
	30	3.6165.130		65	3.6169.165
6.5	35	3.6165.135	13.5	70	3.6169.170
	40	3.6165.140		75	3.6169.175
	45	3.6165.145		80	3.6169.180
	50	3.6165.150		85	3.6169.185
	55	3.6165.155		90	3.6169.190
7	60	3.6165.160	14.5	95	3.6169.195
	65	3.6165.165		100	3.6169.001
	25	3.6166.125		25	3.6149.125
	30	3.6166.130		30	3.6149.130
	35	3.6166.135		35	3.6149.135
7.5	40	3.6166.140	15.5	40	3.6149.140
	45	3.6166.145		45	3.6149.145
	50	3.6166.150		50	3.6149.150
	55	3.6166.155		55	3.6149.155
	60	3.6166.160		60	3.6149.160
8	65	3.6166.165	16.5	65	3.6149.165
	25	3.6167.125		70	3.6149.170
	30	3.6167.130		75	3.6149.175
	35	3.6167.135		80	3.6149.180
	40	3.6167.140		85	3.6149.185
8.5	45	3.6167.145	17.5	90	3.6149.190
	50	3.6167.150		95	3.6149.195
	55	3.6167.155		100	3.6149.001
	60	3.6167.160			
	65	3.6167.165			
9	70	3.6167.170			
	75	3.6167.175			
	80	3.6167.180			
	85	3.6167.185			
	90	3.6167.190			

CHARSPINE2 LOCKING SCREW

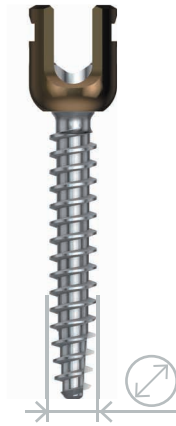


Ti	
3.6160.000	✓



CHARSPINE2 POLYAXIAL SCREW

CHARSPINE system 2



	Len	Ti		Len	Ti
4	25	3.6170.025	8.5	25	3.6530.025
	30	3.6170.030		30	3.6530.030
	35	3.6170.035		35	3.6530.035
	40	3.6170.040		40	3.6530.040
	45	3.6170.045		45	3.6530.045
4.5	25	3.6171.025	9.5	50	3.6530.050
	30	3.6171.030		55	3.6530.055
	35	3.6171.035		60	3.6530.060
	40	3.6171.040		65	3.6530.065
	45	3.6171.045		70	3.6530.070
5	25	3.6172.025	10.5	75	3.6530.075
	30	3.6172.030		80	3.6530.080
	35	3.6172.035		85	3.6530.085
	40	3.6172.040		90	3.6530.090
	45	3.6172.045		95	3.6530.095
5.5	50	3.6172.050	100	100	3.6530.100
	25	3.6173.025		25	3.6531.025
	30	3.6173.030		30	3.6531.030
	35	3.6173.035		35	3.6531.035
	40	3.6173.040		40	3.6531.040
6	45	3.6173.045	10.5	45	3.6531.045
	50	3.6173.050		50	3.6531.050
	55	3.6173.055		55	3.6531.055
	25	3.6174.025		60	3.6531.060
	30	3.6174.030		65	3.6531.065
6.5	35	3.6174.035	10.5	70	3.6531.070
	40	3.6174.040		75	3.6531.075
	45	3.6174.045		80	3.6531.080
	50	3.6174.050		85	3.6531.085
	55	3.6174.055		90	3.6531.090
7	60	3.6174.060	10.5	95	3.6531.095
	65	3.6174.065		100	3.6531.100
	25	3.6175.025		25	3.6532.025
	30	3.6175.030		30	3.6532.030
	35	3.6175.035		35	3.6532.035
7.5	40	3.6175.040	10.5	40	3.6532.040
	45	3.6175.045		45	3.6532.045
	50	3.6175.050		50	3.6532.050
	55	3.6175.055		55	3.6532.055
	60	3.6175.060		60	3.6532.060
8	65	3.6175.065	10.5	65	3.6532.065
	25	3.6176.025		70	3.6532.070
	30	3.6176.030		75	3.6532.075
	35	3.6176.035		80	3.6532.080
	40	3.6176.040		85	3.6532.085
8.5	45	3.6176.045	10.5	90	3.6532.090
	50	3.6176.050		95	3.6532.095
	55	3.6176.055		100	3.6532.100
	60	3.6176.060			
	65	3.6176.065			
9	70	3.6176.070			
	75	3.6176.075			
	80	3.6176.080			
	85	3.6176.085			
	90	3.6176.090			

CHARSPINE2 LOCKING SCREW



Ti



3.6160.000



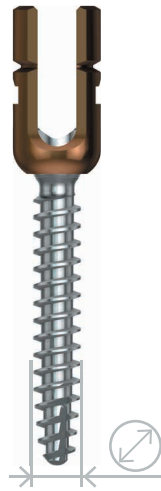
Ø4 Ø4.5 Ø5 Ø5.5 Ø6 Ø6.5 Ø7.5 Ø8.5 Ø9.5 Ø10.5

Colors



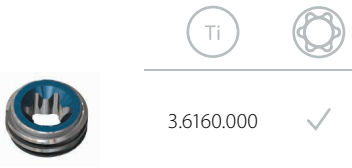
CHARSPINE2 POLYAXIAL REDUCTION SCREW

CHARSPINE *system 2*



	Len	Ti		Len	Ti
4	25	3.6177.025	8.5	25	3.6533.025
	30	3.6177.030		30	3.6533.030
	35	3.6177.035		35	3.6533.035
	40	3.6177.040		40	3.6533.040
	45	3.6177.045		45	3.6533.045
4.5	25	3.6178.025	9.5	50	3.6533.050
	30	3.6178.030		55	3.6533.055
	35	3.6178.035		60	3.6533.060
	40	3.6178.040		65	3.6533.065
	45	3.6178.045		70	3.6533.070
5	25	3.6179.025	10.5	75	3.6533.075
	30	3.6179.030		80	3.6533.080
	35	3.6179.035		85	3.6533.085
	40	3.6179.040		90	3.6533.090
	45	3.6179.045		95	3.6533.095
5.5	50	3.6179.050	10.5	100	3.6533.100
	25	3.6180.025		25	3.6534.025
	30	3.6180.030		30	3.6534.030
	35	3.6180.035		35	3.6534.035
	40	3.6180.040		40	3.6534.040
6	45	3.6180.045	10.5	45	3.6534.045
	50	3.6180.050		50	3.6534.050
	55	3.6180.055		55	3.6534.055
	60	3.6181.060		60	3.6534.060
	65	3.6181.065		65	3.6534.065
6.5	25	3.6181.025	10.5	70	3.6534.070
	30	3.6181.030		75	3.6534.075
	35	3.6181.035		80	3.6534.080
	40	3.6181.040		85	3.6534.085
	45	3.6181.045		90	3.6534.090
7	50	3.6181.050	10.5	95	3.6534.095
	55	3.6181.055		100	3.6534.100
	25	3.6182.025		25	3.6535.025
	30	3.6182.030		30	3.6535.030
	35	3.6182.035		35	3.6535.035
7.5	40	3.6182.040	10.5	40	3.6535.040
	45	3.6182.045		45	3.6535.045
	50	3.6182.050		50	3.6535.050
	55	3.6182.055		55	3.6535.055
	60	3.6182.060		60	3.6535.060
8	65	3.6182.065	10.5	65	3.6535.065
	70	3.6182.070		70	3.6535.070
	75	3.6182.075		75	3.6535.075
	80	3.6183.080		80	3.6535.080
	85	3.6183.085		85	3.6535.085
8.5	90	3.6183.090	10.5	90	3.6535.090
	95	3.6183.095		95	3.6535.095
	100	3.6183.100		100	3.6535.100

CHARSPINE2 LOCKING SCREW



3.6160.000

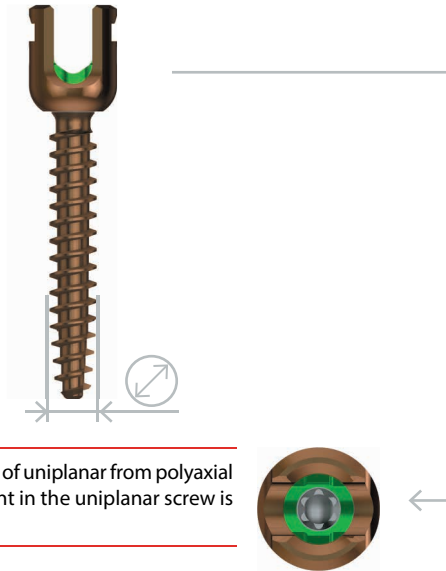
Ø4 Ø4.5 Ø5 Ø5.5 Ø6 Ø6.5 Ø7.5 Ø8.5 Ø9.5 Ø10.5

Colors



CHARSPINE2 UNIPLANAR SCREW

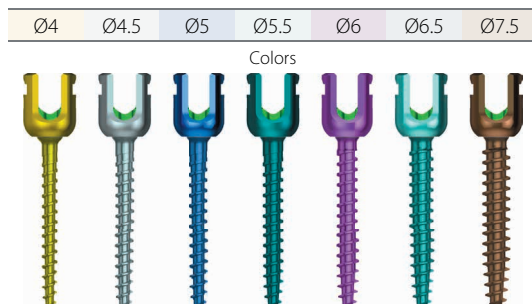
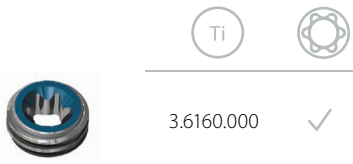
CHARSPINE *system 2*



i For the visual distinction of uniplanar from polyaxial screws, the inner element in the uniplanar screw is green anodized.

Ø	Len	Ti
4	25	3.6184.025
	30	3.6184.030
	35	3.6184.035
	40	3.6184.040
	45	3.6184.045
4.5	25	3.6185.025
	30	3.6185.030
	35	3.6185.035
	40	3.6185.040
	45	3.6185.045
5	25	3.6186.025
	30	3.6186.030
	35	3.6186.035
	40	3.6186.040
	45	3.6186.045
5.5	50	3.6186.050
	25	3.6187.025
	30	3.6187.030
	35	3.6187.035
	40	3.6187.040
6	45	3.6187.045
	50	3.6187.050
	55	3.6187.055
	25	3.6188.025
	30	3.6188.030
6.5	35	3.6188.035
	40	3.6188.040
	45	3.6188.045
	50	3.6188.050
	55	3.6188.055
7	60	3.6188.060
	65	3.6188.065
	25	3.6189.025
	30	3.6189.030
	35	3.6189.035
7.5	40	3.6189.040
	45	3.6189.045
	50	3.6189.050
	55	3.6189.055
	60	3.6189.060
8	65	3.6189.065
	25	3.6190.025
	30	3.6190.030
	35	3.6190.035
	40	3.6190.040
9	45	3.6190.045
	50	3.6190.050
	55	3.6190.055
	60	3.6190.060
	65	3.6190.065
10	70	3.6190.070
	75	3.6190.075
	80	3.6190.080
	85	3.6190.085
	90	3.6190.090

CHARSPINE2 LOCKING SCREW

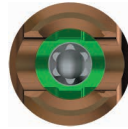


CHARSPINE2 UNIPLANAR REDUCTION SCREW

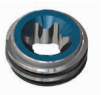
CHARSPINE *system 2*



For the visual distinction of uniplanar from polyaxial screws, the inner element in the uniplanar screw is green anodized.



CHARSPINE2 LOCKING SCREW



Ti



3.6160.000



Ø4 Ø4.5 Ø5 Ø5.5 Ø6 Ø6.5 Ø7.5

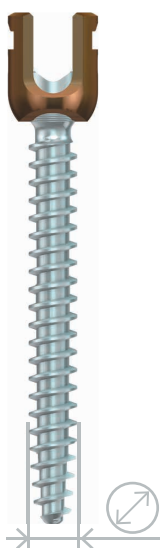
Colors



	Len	Ti
4	25	3.6191.025
	30	3.6191.030
	35	3.6191.035
	40	3.6191.040
	45	3.6191.045
4.5	25	3.6192.025
	30	3.6192.030
	35	3.6192.035
	40	3.6192.040
	45	3.6192.045
5	25	3.6193.025
	30	3.6193.030
	35	3.6193.035
	40	3.6193.040
	45	3.6193.045
5.5	25	3.6193.050
	30	3.6193.055
	35	3.6194.025
	40	3.6194.030
	45	3.6194.035
6	40	3.6194.040
	45	3.6194.045
	50	3.6194.050
	55	3.6194.055
	60	3.6194.060
6.5	65	3.6195.025
	70	3.6195.030
	75	3.6195.035
	80	3.6195.040
	85	3.6195.045
7.5	90	3.6195.050
	25	3.6195.055
	30	3.6195.060
	35	3.6195.065
	40	3.6196.025
8	45	3.6196.030
	50	3.6196.035
	55	3.6196.040
	60	3.6196.045
	65	3.6196.050
9	70	3.6196.055
	75	3.6196.060
	80	3.6196.065
	85	3.6197.025
	90	3.6197.030
10	95	3.6197.035
	100	3.6197.040
	105	3.6197.045
	110	3.6197.050
	115	3.6197.055
11	120	3.6197.060
	125	3.6197.065
	130	3.6197.070
	135	3.6197.075
	140	3.6197.080
12	145	3.6197.085
	150	3.6197.090
	155	3.6197.095
	160	3.6197.100
	165	3.6197.105

CHARSPINE2 POLYAXIAL SCREW FOR PELVIS

CHARSPINE *system 2*

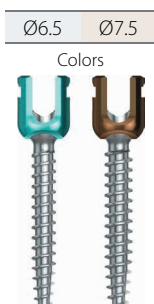


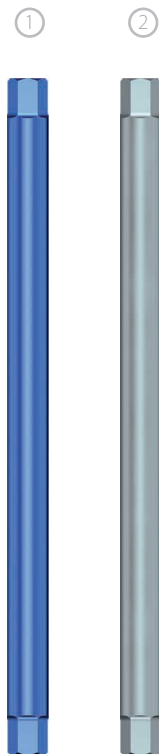
	Len	Ti
6.5	25	3.6514.025
	30	3.6514.030
	35	3.6514.035
	40	3.6514.040
	45	3.6514.045
	50	3.6514.050
	55	3.6514.055
	60	3.6514.060
	65	3.6514.065
	70	3.6514.070
	75	3.6514.075
	80	3.6514.080
	85	3.6514.085
	90	3.6514.090
	7.5	25
30		3.6515.030
35		3.6515.035
40		3.6515.040
45		3.6515.045
50		3.6515.050
55		3.6515.055
60		3.6515.060
65		3.6515.065
70		3.6515.070
75		3.6515.075
80		3.6515.080
85		3.6515.085
90		3.6515.090

CHARSPINE2 LOCKING SCREW



Ti	
3.6160.000	✓



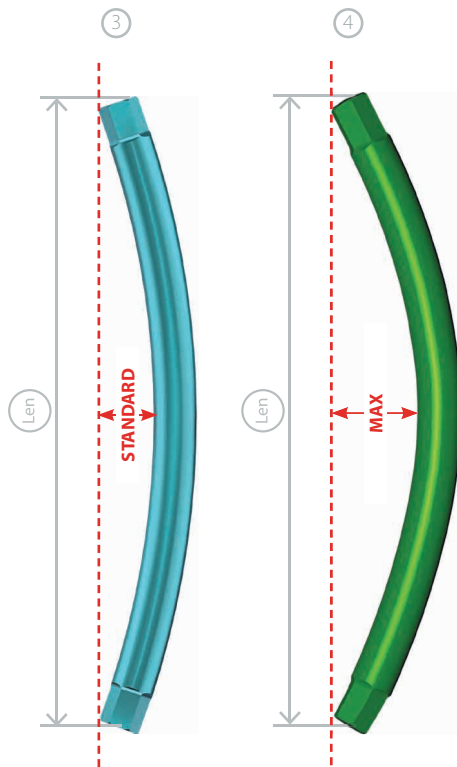
CHARSPINE *system 2*

①	Len	Ti
	40	3.3246.040
	50	3.3246.050
	60	3.3246.060
	70	3.3246.070
	80	3.3246.080
	90	3.3246.090
	100	3.3246.100
	120	3.3246.120
	160	3.3246.160
	200	3.3246.200
	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

②	Len	Co
	40	4.3980.040
	50	4.3980.050
	60	4.3980.060
	70	4.3980.070
	80	4.3980.080
	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 6

CHARSPINE *system 2*



3

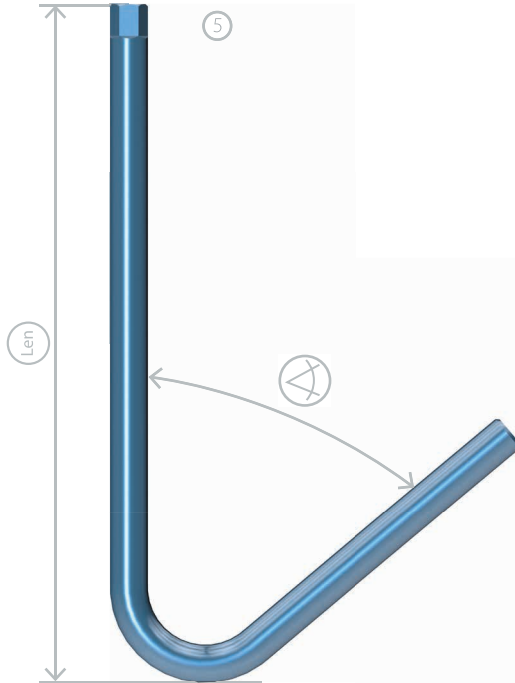
Len	Ti
35	3.6280.035
40	3.6280.040
45	3.6280.045
50	3.6280.050
55	3.6280.055
60	3.6280.060
65	3.6280.065
70	3.6280.070
75	3.6280.075
80	3.6280.080
85	3.6280.085

4

Len	Ti
35	3.6295.035
40	3.6295.040
45	3.6295.045
50	3.6295.050
55	3.6295.055
60	3.6295.060
65	3.6295.065
70	3.6295.070
75	3.6295.075
80	3.6295.080
85	3.6295.085

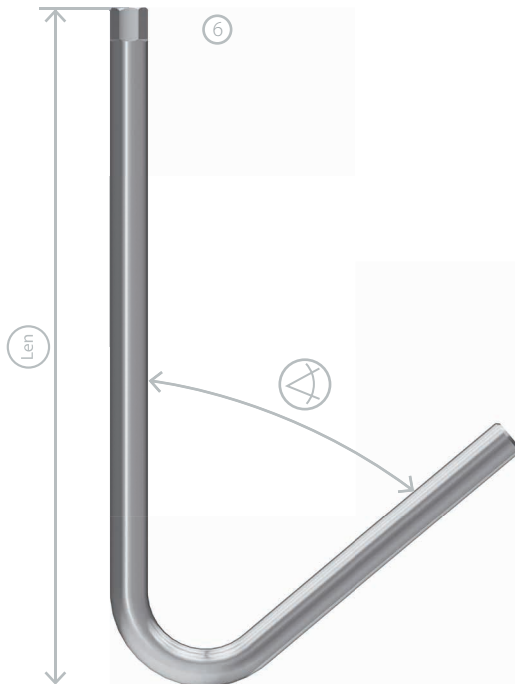
ANGLED ROD 6

CHARSPINE *system 2*



5

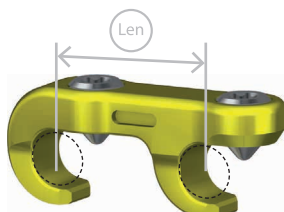
	Len	Ti
50°	150	3.3981.155
	200	3.3981.205
	250	3.3981.255
	300	3.3981.305
	350	3.3981.355
60°	450	3.3981.455
	150	3.3981.156
	200	3.3981.206
	250	3.3981.256
	300	3.3981.306
70°	350	3.3981.356
	450	3.3981.456
	150	3.3981.157
	200	3.3981.207
	250	3.3981.257
70°	300	3.3981.307
	350	3.3981.357
	450	3.3981.456



6

	Len	Co
50°	150	4.3981.155
	200	4.3981.205
	250	4.3981.255
	300	4.3981.305
	350	4.3981.355
60°	450	4.3981.455
	150	4.3981.156
	200	4.3981.206
	250	4.3981.256
	300	4.3981.306
70°	350	4.3981.356
	450	4.3981.456
	150	4.3981.157
	200	4.3981.207
	250	4.3981.257
70°	300	4.3981.307
	350	4.3981.357
	450	4.3981.456

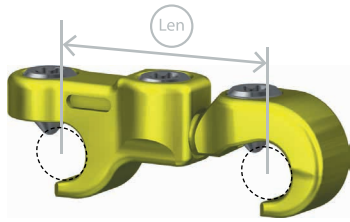
CROSSWISE CONNECTOR SOLID (SET)

CHARSPINE *system 2*

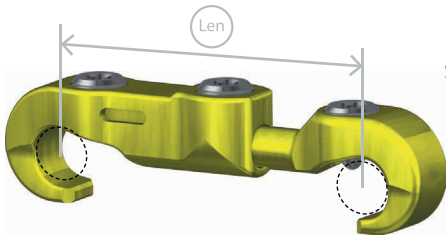
Len	Ti
14	3.6290.014
15	3.6290.015
16	3.6290.016
17	3.6290.017
18	3.6290.018
19	3.6290.019
20	3.6290.020
21	3.6290.021
22	3.6290.022
23	3.6290.023
24	3.6290.024
25	3.6290.025
26	3.6290.026
27	3.6290.027
28	3.6290.028
29	3.6290.029
30	3.6290.030

CROSSWISE CONNECTOR REGULATED (SET)

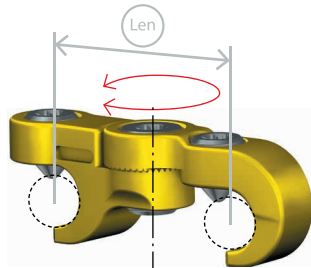
CHARSPINE *system 2*



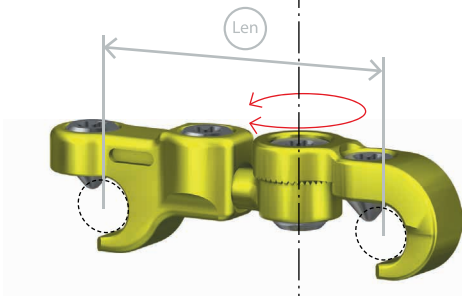
XS



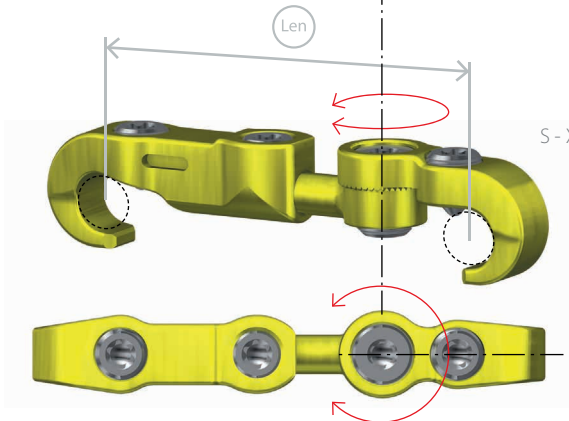
S - XL



XS



XS



S - XL

	Len	Ti
XS	26-30.5	3.3979.026

	Len	Ti
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

	Len	Ti
XS	22	3.6296.022
	24	3.6296.024
	26	3.6296.026
	28	3.6296.028
	30	3.6296.030
	32	3.6296.032
	34	3.6296.034

	Len	Ti
XS	33-37.5	3.3972.033

	Len	Ti
S	37.5-40	3.3972.037
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)

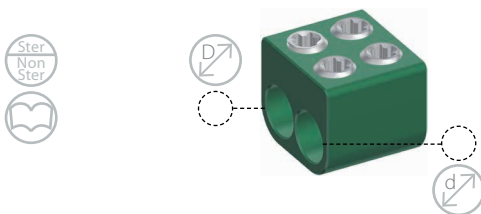
CHARSPINE *system 2*



d	D	Ti
5	5	3.3970.855
6	5	3.3970.865
6	6	3.3970.866

PARALLEL CONNECTOR (SET)

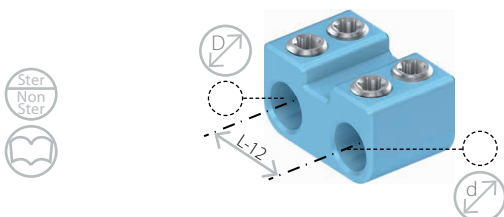
CHARSPINE *system 2*



d	D	Ti
5	5	3.3970.955
6	5	3.3970.965
6	6	3.3970.966

PARALLEL CONNECTOR (SET)

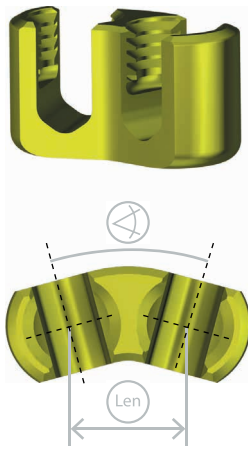
CHARSPINE *system 2*





d	D	Ti
6	6	3.6294.012

ANGULAR CONNECTOR



CHARSPINE *system 2*



	 Len	
0°	12	3.6284.012
	16	3.6284.016
10°	12	3.6285.012
	16	3.6285.016
30°	12	3.6286.012
	16	3.6286.016

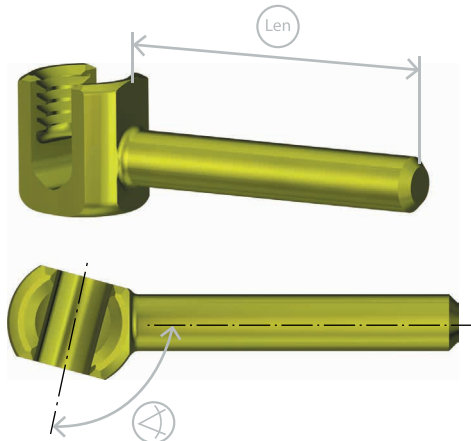
CHARSPINE2 LOCKING SCREW





	
3.6160.000	✓

LATERAL CONNECTOR



CHARSPINE *system 2*



	 Len	
90°	15	3.6281.015
	20	3.6281.020
	25	3.6281.025
	30	3.6281.030
	35	3.6281.035
75°	15	3.6282.015
	20	3.6282.020
	25	3.6282.025
	30	3.6282.030
	35	3.6282.035
105°	15	3.6283.015
	20	3.6283.020
	25	3.6283.025
	30	3.6283.030
	35	3.6283.035

CHARSPINE2 LOCKING SCREW



	
3.6160.000	✓

CLAMP CROSSWISE CONNECTOR (SET)

CHARSPINE *system 2*

Ti

3.6287.000

LATERAL CONNECTOR

CHARSPINE *system 2*

Len

Ti

Len	Ti
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

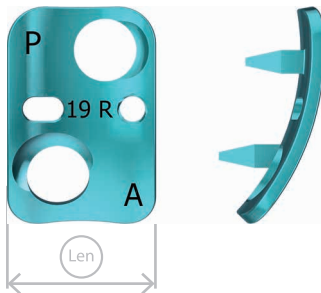
SINGLE-HOLE STAPLE

CHARSPINE *system 2*

Ti

3.6291.000

DOUBLE-HOLE STAPLE ROSTRAL

CHARSPINE *system 2*

Len

Ti

19

3.6292.016

21

3.6292.021

23

3.6292.023

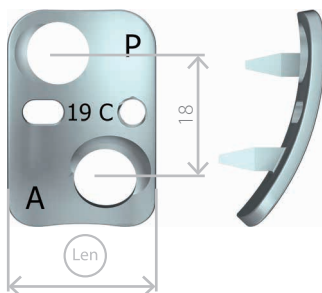
25

3.6292.025

27

3.6292.027

DOUBLE-HOLE STAPLE CAUDAL

CHARSPINE *system 2*

Len

Ti

19

3.6293.016

21

3.6293.021

23

3.6293.023













25

3.6293.025

27

3.6293.027







Small	Standard	Large
Laminar hook		
 <p>3.6266.001</p>	 <p>3.6266.002</p>	 <p>3.6266.003</p>
Laminar hook, narrow blade		
 <p>3.6267.001</p>	 <p>3.6267.002</p>	 <p>3.6267.003</p>
Laminar hook, extended body		
<p>3.6268.001*</p>	 <p>3.6268.002</p>	<p>3.6268.003*</p>
Laminar hook, offset		
<p>3.6269.001 – right * 3.6269.101 – left *</p>	 <p>3.6269.002 – right 3.6269.102 – left</p>	<p>3.6269.003 – right * 3.6269.103 – left *</p>
Laminar hook, angled blade		
<p>3.6270.001*</p>	 <p>3.6270.002</p>	<p>3.6270.003*</p>
Thoracic laminar hook		
	 <p>3.6271.002</p>	
Thoracic laminar hook, narrow blade		
	 <p>3.6272.002</p>	
Thoracic laminar hook, offset		
	 <p>3.6273.002 – Small offset, right; 3.6273.102 – Small offset, left; 3.6274.002 – Large offset, right; 3.6274.102 – Large offset, left;</p>	

* available as additional item

SPINAL HOOKS

CHARSPINE *system 2*

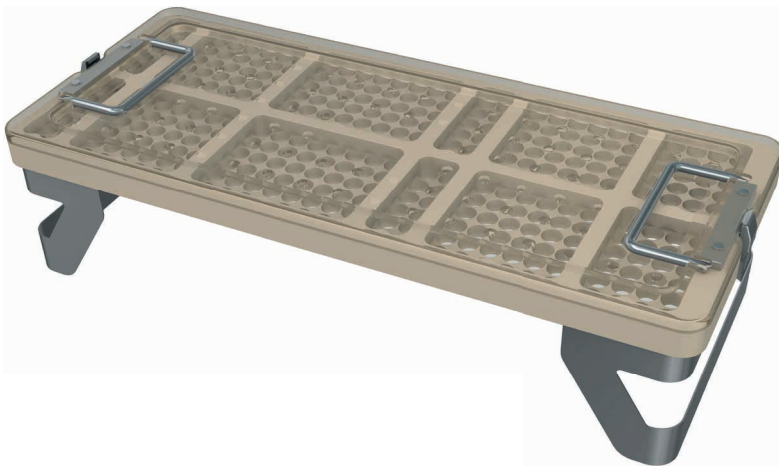
Small	Standard	Large
Pedicule hook		
 3.6275.001	 3.6275.002	 3.6275.003*
Transverse process hook		
3.6276.001 – right* 3.6276.101 – left*	 3.6276.002 – right 3.6276.102 – left	3.6276.003 – right* 3.6276.103 – left*

* available as additional item



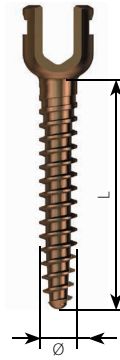
The palettes for implants presented below are not offered as sets (they do not include implants).

40.8064.000
PALETTE FOR CHARSPINE2 IMPLANTS - SCREWS

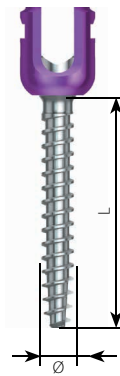


Screw diameter	Size L	No. of sockets
4.5	25	2
	30	2
	35	2
	40	2
	45	2
	50	2
5.0	35	2
	40	2
	45	2
	50	2
	55	2
	60	2
5.5	30	8
	35	8
	40	8
	45	8
	50	8
	55	8
6.0	35	8
	40	8
	45	8
	50	8
	55	8
	60	8
6.5	35	6
	40	6
	45	6
	50	6
	55	6
	60	6
7.5	35	6
	40	6
	45	6
	50	6
	55	6
	60	6
8.5	50	2
	55	2
	60	2
	70	2
	80	2
	90	2
9.5	50	2
	55	2
	60	2
	70	2
	80	2
	90	2
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

Monoaxial screws



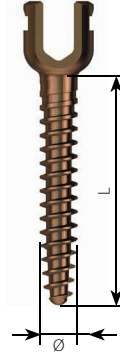
Polyaxial screws



40.8119.000
PALETTE SMALL FOR CHARSPINE2 IMPLANTS - SCREWS

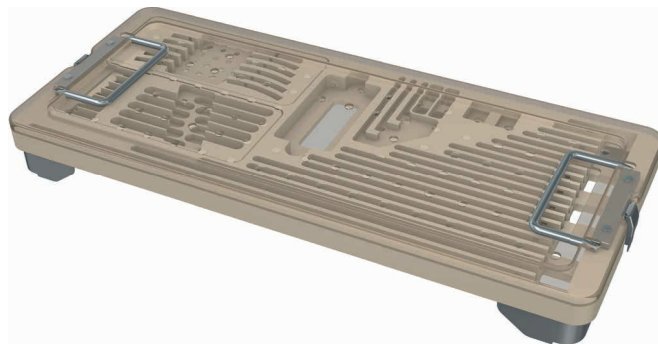


Monoaxial, polyaxial and uniplanar screws



Screw diameter	Size L	No. of sockets
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
6.5	60	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

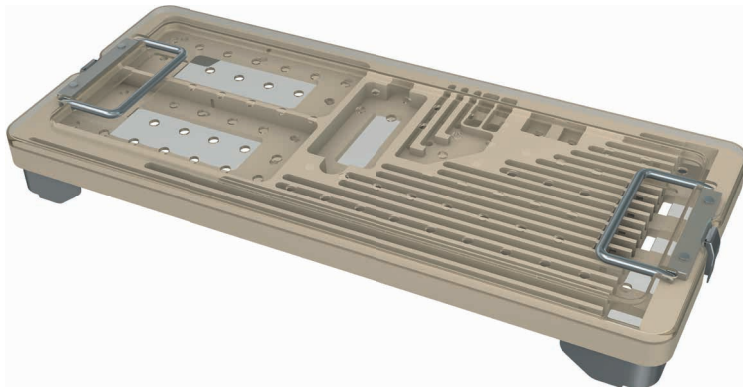


40.8078.000
 Exchangeable module 1



40.8080.000
 Exchangeable module 3

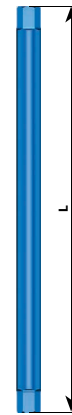
40.8065.000
Palette for CHARSPINE2 implants - Connectors 1



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
---	----

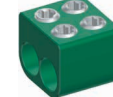


Axial connector



6/6	1
-----	---

Parallel connector



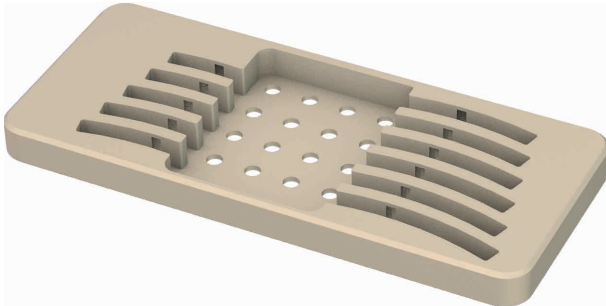
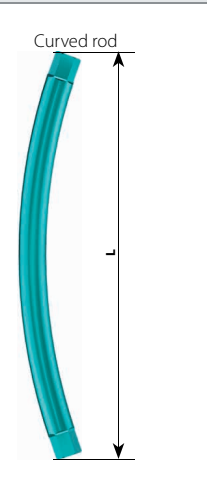
6/6	1
-----	---

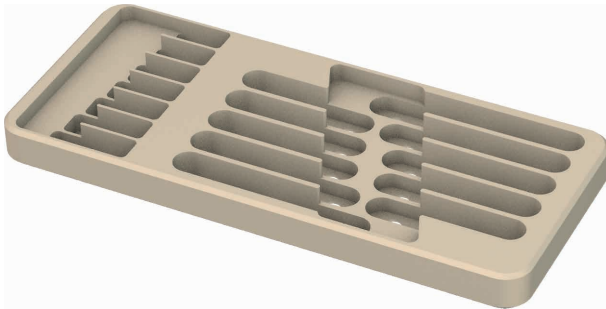


Clamp crosswise connector



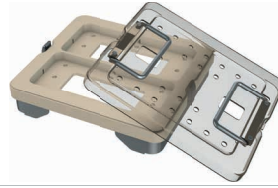
-	4
---	---

EXCHANGEABLE MODULES – IMPLANT SOCKETS CONFIGURATION

40.8078.000 Exchangeable module 1	Implant type	Size	No. of sockets
		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	
	 <p data-bbox="1021 963 1220 990">Crosswise connector solid</p>	L-14	1	
		L-15	1	
		L-16	1	
		L-17	1	
		L-18	1	
		L-19	1	
		L-20	1	
		 <p data-bbox="1005 1142 1236 1191">Crosswise connector regulated (monoaxial)</p>	XS	1
			S	1
			M	1
		 <p data-bbox="1013 1299 1228 1326">Lateral connector (polyaxial)</p>	L	1
			XL	1
			XS	1
			S	1
		M	1	
L	1			
XL	1			

MODULAR PALETTE FOR CHARSPINE2 IMPLANTS - CONNECTORS 2 (STANDARD CONFIGURATION)



40.8066.000
Palette for **CHARSPINE2** implants - Connectors 2



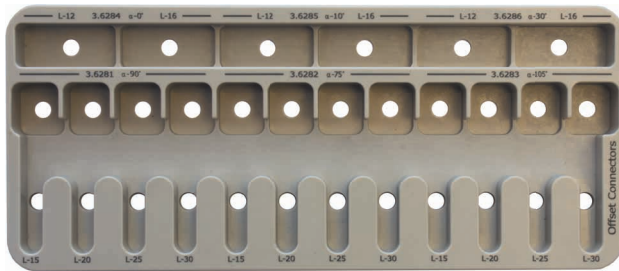
40.8081.000
Exchangeable module 4



40.8079.000
Exchangeable module 2

EXCHANGEABLE MODULES – IMPLANT SOCKETS CONFIGURATION

40.8081.000
Exchangeable module 4



Implant type

Size

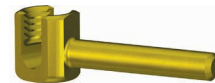
No. of sockets

Angular connector



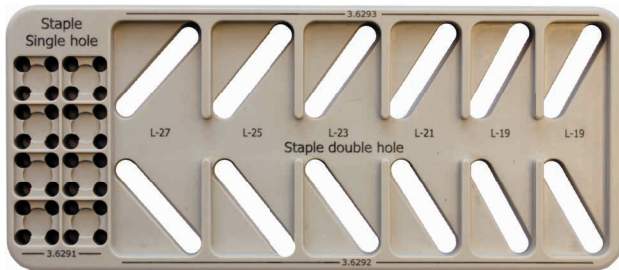
L-12	1
L-16	1
10° L-12	1
10° L-16	1
30° L-12	1
30° L-16	1
90° L-15	1
90° L-20	1
90° L-25	1

Lateral connector



90° 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

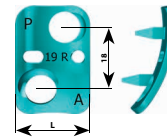
No. of sockets

Single-hole staple



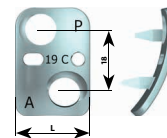
-	8
---	---

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





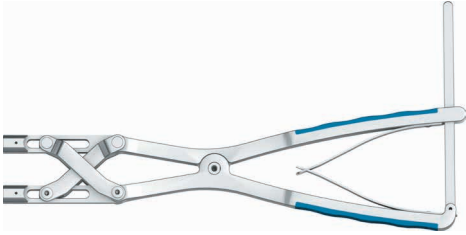
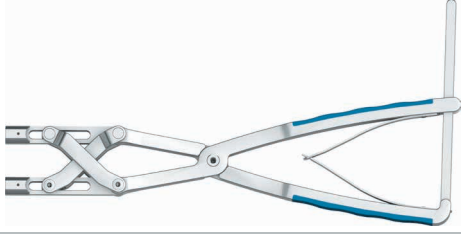







It is possible to change the configuration of modules included into palettes according to an individual order.

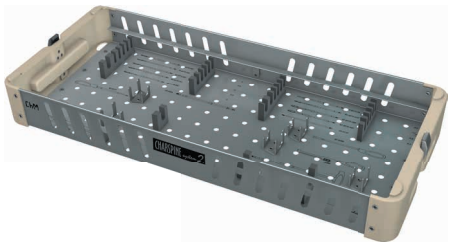


















40.8077.000
Palette for CHARSPINE2 implants - Hooks


	Implant type	Variant	No. of sockets
	Laminar hook	Small	6
		Standard	6
		Large	6
	Laminar hook, narrow blade	Small	6
		Standard	6
		Large	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
	Pedicule hook	Small	2
		Standard	2
	Transverse process hook	Right	3
		Left	3

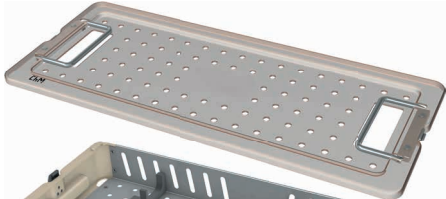


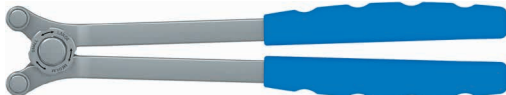








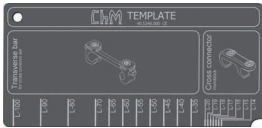

III. INSTRUMENTS

Instrument set for CHARSPINE2 spine stabilizer - basic [15.0907.001]			
Instrument set for CHARSPINE2 module 1 [15.0907.104]	Name	Catalogue no.	Pcs
	Container lid 9x4	14.0907.104	1
	Container 9x4H	14.0907.101	1
	Compression forceps-jaws W-26 (set) Exchangeable compression jaws are used with compression forceps.	40.5768.026	1
	Compression forceps-jaws W-46 (set) Exchangeable compression jaws are used with compression forceps.	40.5768.046	1
	Distraction forceps-jaws Exchangeable distraction jaws are used with distraction forceps.	40.5769.000	1
	Parallel distraction forceps Distraction forceps are used with exchangeable jaws and are intended for procedure of vertebrae distraction.	40.8093.000	1
	Parallel compression forceps Compression forceps are used with exchangeable jaws and are intended for procedure of vertebrae compression.	40.8094.000	1
	Counter wrench Counter wrench is used to ensure rotational stability of the implants system during final tightening of the locking screws.	40.8095.000	1
	Rod bender 6.0 left Bender is used for bending the rod in situ.	40.8091.000	1
	Rod bender 6.0 right Bender is used for bending the rod in situ.	40.8092.000	1
	Pedicle probe straight Pedicle probe is used to verify the continuity of the vertebral arch pedicle.	40.6698.000	1
	Pedicle probe curved Pedicle probe is used to verify the continuity of the vertebral arch pedicle.	40.6699.000	1



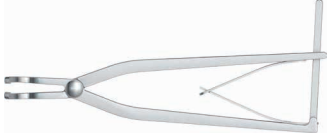


Instrument set for CHARSPINE2 spine stabilizer - basic [15.0907.001]

Instrument set for CHARSPINE2 module 2 [15.0907.102]	Name	Catalogue no.	Pcs
	Container 9x4H	14.0907.102	1
	Cortical tap 4.0	40.8075.040	1
	Cortical tap 4.5	40.8075.045	1
	Cortical tap 5.0	40.8075.050	1
	Cortical tap 5.5	40.8075.055	1
	Cortical tap 6.0	40.8075.060	1
	Cortical tap 6.5	40.8075.065	1
	Cortical tap 7.5	40.8075.075	1
	Cortical tap 8.5	40.8075.085	1
	Cortical tap 9.5	40.8075.095	1
	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.		
	Screwdriver tip T30 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.	40.8084.000	1
	Screwdriver T30 Screwdriver T30 is used for application and initial locking of the locking screws.	40.8111.000	1
	Reduction screw device Reduction screw device is used to break off the extended arms of reduction screws.	40.8108.000	1
	Eye wrench Eye wrench is used to prevent the rod from changing its position while bending, and to conduct the rod derotation.	40.8069.000	1
	Rod impactor Rod impactor is used to impact and press the rod down to the transpedicular screw cut-out.	40.8068.000	1
	Impactor for staples Impactor for staples is used for insertion and positioning of double-hole staples.	40.8098.000	1
	Screwdriver tip T15 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.	40.8110.000	1
	Trocar Trocar is used to puncture the cortical layer of the vertebral arch pedicle, as a point of insertion of transpedicular screw.	40.8073.000	1
	Fork persuader Fork persuader is used to press the rod down to the bottom of the transpedicular screw cut-out.	40.8100.000	1





Instrument set for CHARSPINE2 spine stabilizer - basic [15.0907.001]

Instrument set for CHARSPINE2 module 3 [15.0907.103]	Name	Catalogue no.	Pcs
	Container lid 9x4	14.0907.104	1
	Container 9x4H	14.0907.103	1
	Screw persuader Screw persuader is used to press the rod down to the bottom of the transpedicular screw cut-out.	40.8096.100	1
	Adjustable rod bender Adjustable rod bender is used to bend the rod to desired shape	40.8074.000	1
	Oval head ratchet handle Oval head ratchet handle is used with wrenches for screws and cortical taps (interchangeably with T-type ratchet handle 40.8085.000).	40.8086.000	1
	Wrench for monoaxial screws 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.	40.8089.100	1
	Wrench for polyaxial screws 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.	40.8090.100	1
	Screwdriver tip for monoaxial screws Screwdriver tip for monoaxial screws [40.6145] is a spare instrument for use with wrench for monoaxial screws [40.8089]. This makes it possible to insert two monoaxial screws by two operators simultaneously.	40.6145.000	1
	Screwdriver tip for polyaxial screws Screwdriver tip for polyaxial screws [40.6146] is a spare instrument for use with wrench for polyaxial screws [40.8090]. This makes it possible to insert two polyaxial screws by two operators simultaneously.	40.6146.000	1
	Thoracic pedicular trocar Thoracic pedicular trocar is used to prepare openings in the pedicle of the vertebral arch in the thoracic section of the spine.	40.8070.000	1
	Universal pedicular trocar Universal pedicular trocar is used to prepare openings in the pedicle of the vertebral arch in the lumbar section of the spine.	40.8071.000	1
	Straight pedicular trocar Straight pedicular trocar is used to prepare openings in the pedicle of the vertebral arch in the lumbar section of the spine.	40.8072.000	1
	Template Template is used for selecting the size of crosswise and rod connectors.	40.5248.000	1
	Holding forceps Holding forceps are used to conduct the rod derotation procedure.	40.6202.000	2

Instrument set for CHARSPINE2 spine stabilizer - basic [15.0907.001]

Instrument set for CHARSPINE2 module 4 [15.0907.201]	Name	Catalogue no.	Pcs
	Tray 4x4 1/2H	14.0907.201	1
	Pliers for rod Pliers for rod are used to grab and insert the spinal rod.	40.8109.000	1
	Holder for crosswise connectors Holder for crosswise connectors is used for insertion and mounting of clamp and regulated crosswise connectors.	40.8067.000	1
	Holder for rod connectors с соединителями скобообразными. Holder for rod connectors is used for insertion and mounting of rod connectors (which are mounted together with clamp connectors).	40.8076.000	1
	Staple holder Staple holder is used to insert the single-hole staples.	40.8099.000	1

Instrument set for CHARSPINE2 spine stabilizer - basic [15.0907.001]

Instrument set for CHARSPINE2 module 5 [15.0907.202]	Name	Catalogue no.	Pcs
	Tray 4x4 1/2H	14.0907.202	1
	T-type ratchet handle T-type ratchet handle is used with wrenches for screws and cortical taps.	40.8085.000	1
	T-type torque handle 12Nm T-type torque handle 12Nm is intended to be used with screwdriver tip T30 [40.8084.000] and is used for final tightening of the locking screws into the transpedicular screws, hooks and lateral connectors.	40.8087.000	1
	T-type torque handle 3.5Nm T-type torque handle 3.5Nm is intended to be used only with screwdriver tip T15 [40.8110.000] and is used for final tightening of the locking screws into the crosswise, axial and parallel connectors.	40.8088.000	1

Name	Catalogue no.	Pcs
	Tray 4x1 1/2H	14.0000.201

Instrument set for CHARSPINE2 spine stabilizer - extended 1 [15.0907.002]
(instruments for spine hooks)

Instrument set for CHARSPINE2 module 6 [15.0907.203] **Name** **Catalogue no.** **Pcs**



Tray 5x4 1/2H

14.0907.203

1



Hook holder

Hook holder is used to insert spinal hooks.

40.8101.000

1



Lateral hook holder

Lateral hook holder is used to insert spinal hooks.

40.8102.000

1

Instrument set for CHARSPINE2 spine stabilizer - extended 1 [15.0907.002]
(instruments for spine hooks)

Instrument set for CHARSPINE2 module 7 [15.0907.204] **Name** **Catalogue no.** **Pcs**



Tray 5x4 1/2H

14.0907.204

1



Impactor for hooks

Impactor for hooks is used for final impaction of spinal hook into the selected space.

40.8103.000

1



Narrow raspatory for laminar hooks

Narrow raspatory for laminar hooks is used to prepare space for a laminar hook.

40.8104.000

1



Raspatory for laminar hooks

Raspatory for laminar hooks is used to prepare space for a laminar hook.

40.8105.000

1



Wide raspatory for laminar hooks

Wide raspatory for laminar hooks is used to prepare space for a laminar hook.

40.8106.000

1



Raspatory for pedicle hooks

Raspatory for pedicle hooks is used to prepare space for a pedicular hook.

40.8107.000

1











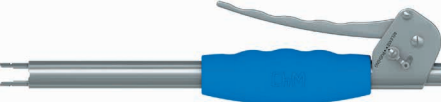



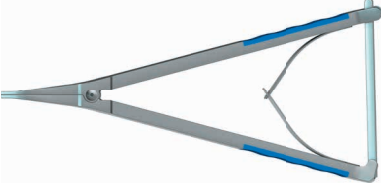


Extended instrument set [15.0907.002] is additional equipment.





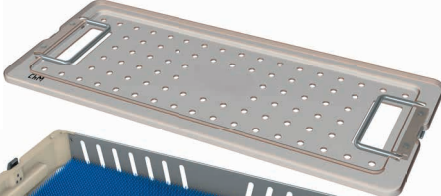
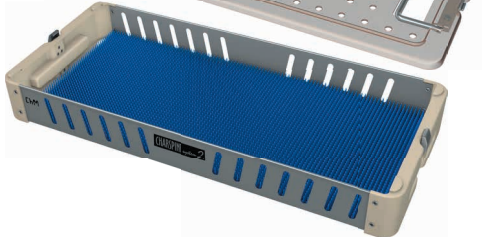
In order to include the instruments to the ordered CHARSPINE2 instruments, please contact your local representative or ChM Sales Department.



Instruments mentioned below are not included in the standard instrument set.

In order to include them to the ordered CHARSPINE2 instruments, please contact your local representative or ChM Sales Department.

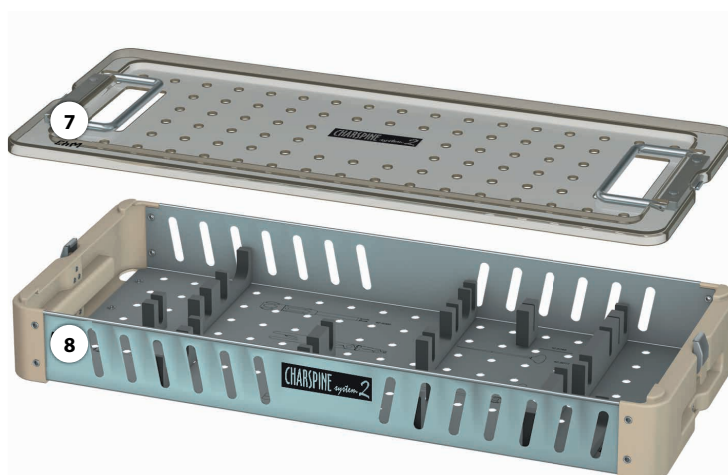
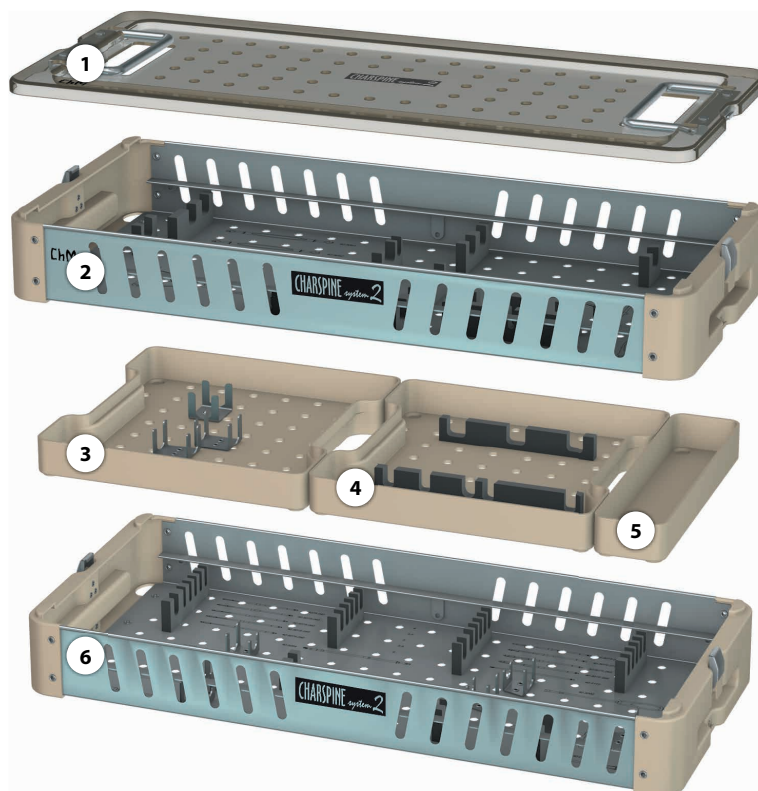
	Name	Catalogue no.
	Wrench for monoaxial screws - mini Wrench for monoaxial screws - mini is used as an alternative to the standard wrench [40.8089.100] in situations where the conditions of surgery or the surgeon's preferences require the use of a very short instrument.	40.6158.100
	Wrench for polyaxial screws - mini Wrench for polyaxial screws - mini is used as an alternative to the standard wrench [40.8090.100] in situations where the conditions of surgery or the surgeon's preferences require the use of a very short instrument.	40.6159.100
	Screwdriver tip for monoaxial screws - mini Screwdriver tip for monoaxial screws - mini is a spare instrument for use with wrench for monoaxial screws - mini [40.6158.100]. This makes it possible to insert two monoaxial screws by two operators simultaneously.	40.6149.000
	Screwdriver tip for polyaxial screws - mini Screwdriver tip for polyaxial screws - mini is a spare instrument for use with wrench for monoaxial screws - mini [40.6159.100]. This makes it possible to insert two monoaxial screws by two operators simultaneously.	40.6150.000
	Wrench for monoaxial screws short Wrench for monoaxial screws short is used as an alternative to the standard wrench 40.8089.100 in situations where the conditions of surgery or the surgeon's preferences require the use of shorter instrument.	40.8112.100
	Wrench for polyaxial screws short Wrench for polyaxial screws short is used as an alternative to the standard wrench 40.8090.100 in situations where the conditions of surgery or the surgeon's preferences require the use of shorter instrument.	40.8113.100
	Screwdriver tip for monoaxial screws short Screwdriver tip for monoaxial screws short [40.6147] is a spare instrument for use with wrench for monoaxial screws short [40.8112]. This makes it possible to insert two monoaxial screws by two operators simultaneously.	40.6147.000
	Screwdriver tip for polyaxial screws short Screwdriver tip for polyaxial screws short [40.6148] is a spare instrument for use with wrench for polyaxial screws short [40.8113]. This makes it possible to insert two polyaxial screws by two operators simultaneously.	40.6148.000
	Screw persuader Screw persuader may be used as an alternative to the standard persuader 40.8096.100. The instrument can be handled using only one hand.	40.8083.100
	Rod trial 6/300 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.	40.5246.300
	Pedicule probe Pedicule probe is used to verify the continuity of the vertebral arch pedicle. The probe is equipped with two tips of different stiffness.	40.6696.000
	Tubular rod bender (2 pcs.) Tubular rod bender is used for bending the rod to the acute angle, especially when stabilization: the sacral bone – iliac ala is performed.	40.6178.000
	Distraction forceps Szczypce dystrykcyjne są używane do przeprowadzenia procedury dystrykcji kręgów.	40.6176.000
	Compression forceps Compression forceps are used for vertebrae compression.	40.6694.000
	Screwdriver T30 short Screwdriver T30 short is used as an alternative to the standard screwdriver T30 [40.8111] in situations where the conditions of surgery or the surgeon's preferences require the use of a shorter instrument.	40.6151.100

	Name	Catalogue no.
	Thoracic pedicular trocar Thoracic pedicular trocar [40.6243] is used as an alternative to the standard thoracic trocar [40.8070] in situations where the surgeon's preferences require the use of an instrument with an oval handle.	40.6243.000
	Universal pedicular trocar Universal pedicular trocar [40.6244] is used as an alternative to the standard universal trocar [40.8071] in situations where the surgeon's preferences require the use of an instrument with an oval handle.	40.6244.000
	Straight pedicular trocar Straight pedicular trocar [40.6245] is used as an alternative to the standard straight trocar [40.8072] in situations where the surgeon's preferences require the use of an instrument with an oval handle.	40.6245.000
	Hand hold rod cutter Hand hold rod cutter is used for easy cutting of rods with diameters of 6mm, 5mm and 3.5mm.	40.5288.000
	Container lid 9x4	14.0907.106
	Container 9x4H Use the container [14.0907.105] with silicone mat [12.0725.000] for storage of the additional instruments (provided on the customer's request) of the CHARSPINE2 system. This container, depending on the needs, can be included into another container of the CHARSPINE2 system or provided with a separate container lid [14.0907.106].	14.0907.105

III.1. CONTAINERS ARRANGEMENT

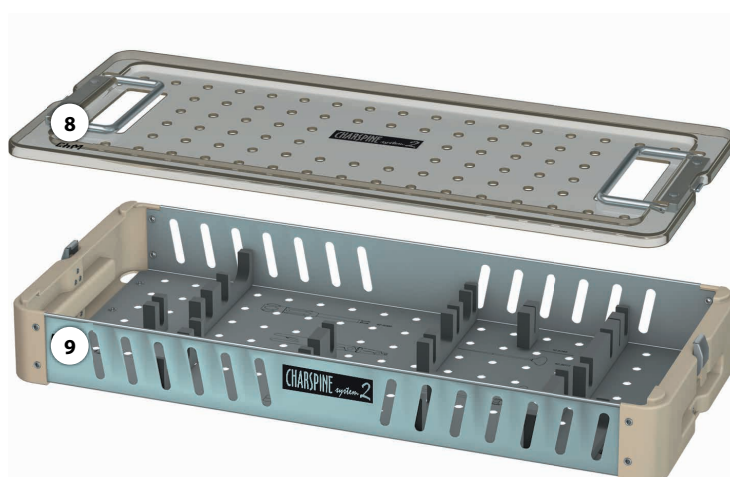
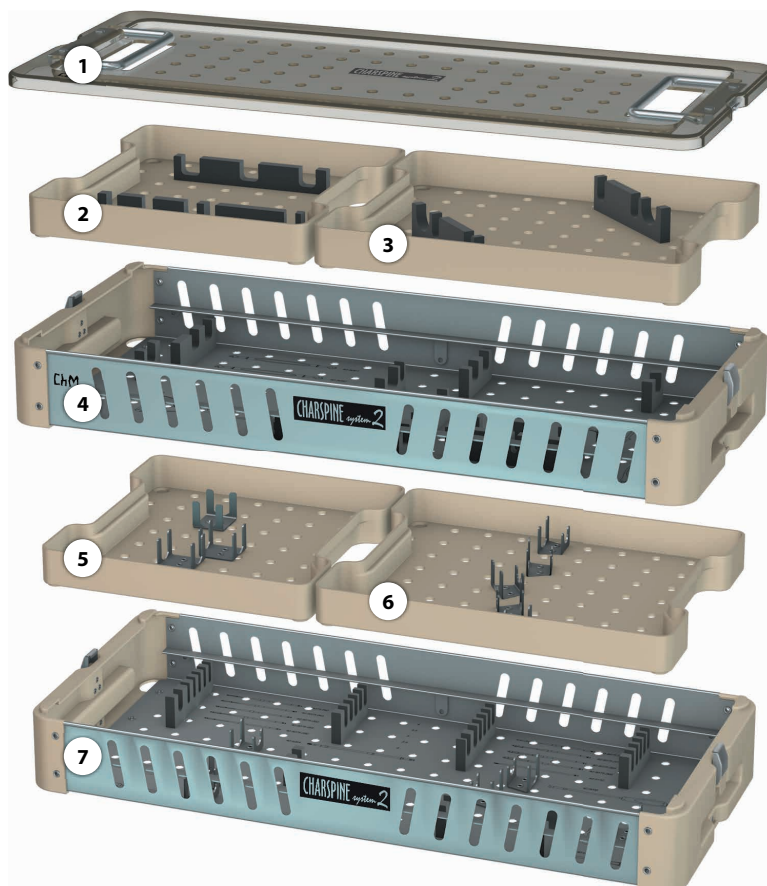
Containers for basic instrument set [15.0907.001]

No.	Name	Catalogue No.	Pcs
1	Container lid 9x4	14.0907.104	1
2	Container 9x4H	14.0907.101	1
3	Tray 4x4 1/2H	14.0907.202	1
4	Tray 4x4 1/2H	14.0907.201	1
5	Tray 4x1 1/2H	14.0000.201	1
6	Container 9x4H	14.0907.102	1
7	Container lid 9x4	14.0907.104	1
8	Container 9x4H	14.0907.103	1



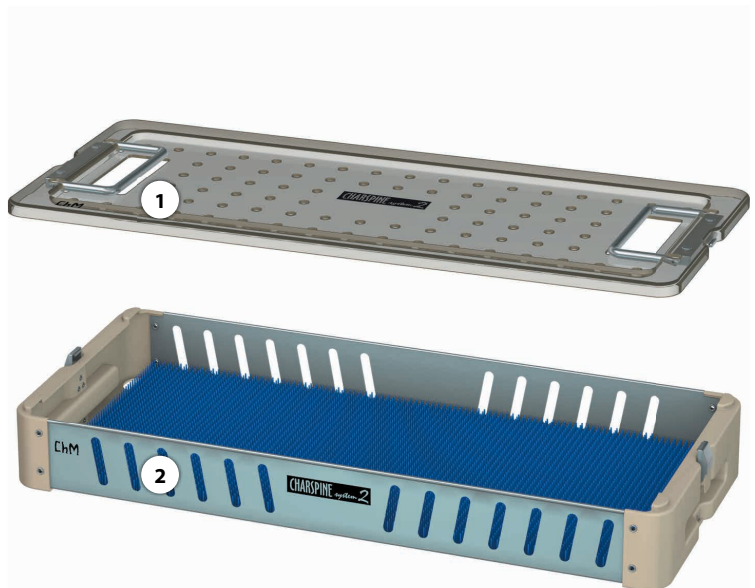
Containers for instrument set:
- basic [15.0907.001], and
- extended 1 [15.0907.002].

No.	Name	Catalogue No.	Pcs
1	Container lid 9x4	14.0907.104	1
2	Tray 4x4 1/2H	14.0907.201	1
3	Tray 5x4 1/2H	14.0907.203	1
4	Container 9x4H	14.0907.101	1
5	Tray 4x4 1/2H	14.0907.202	1
6	Tray 5x4 1/2H	14.0907.204	1
7	Container 9x4H	14.0907.102	1
8	Container lid 9x4	14.0907.104	1
9	Container 9x4H	14.0907.103	1



Container 9x4H [14.0907.105] and container lid 9x4 [14.0907.106] are intended for storing additional instruments of CHARSPINE2 system, completed on a client's request.

No.	Name	Catalogue No.	Pcs
1	Container lid 9x4	14.0907.106	1
2	Container 9x4H	14.0907.105	1



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

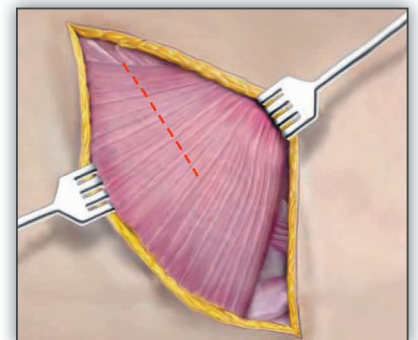
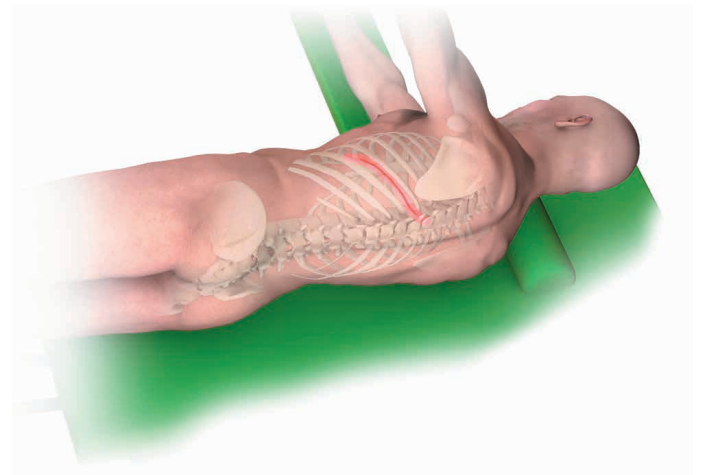
Thoracotomy is a standard approach for the treatment of thoracic spine disorders such as deformity, tumor or infection. In case of deformity treatment, the approach is always located on the side of the curve apex, e.g. a right-sided thoracotomy is chosen for a right-sided curve. In general, a left-sided 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 indications for the 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.

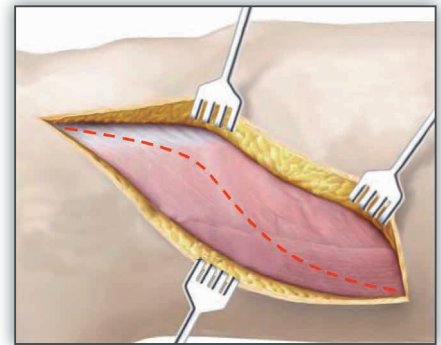
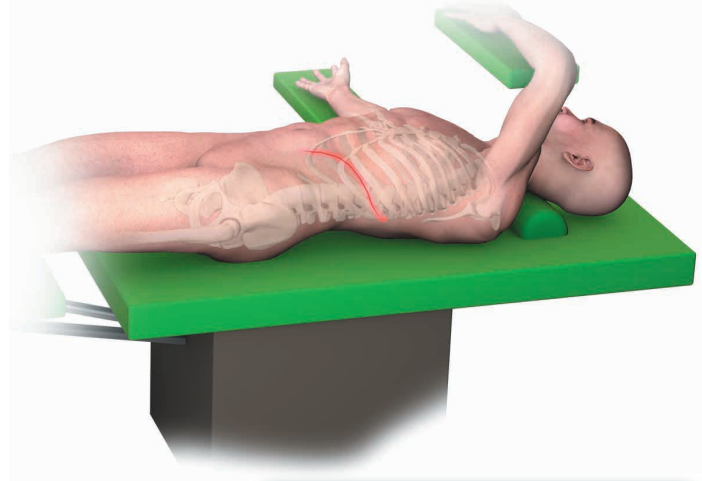
Patient positioning

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

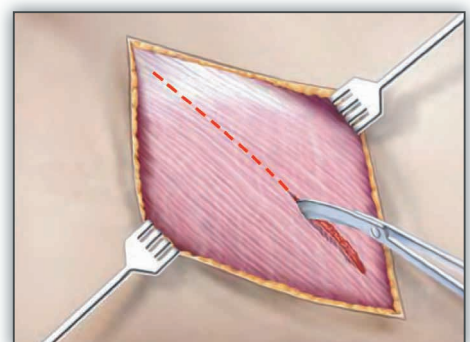
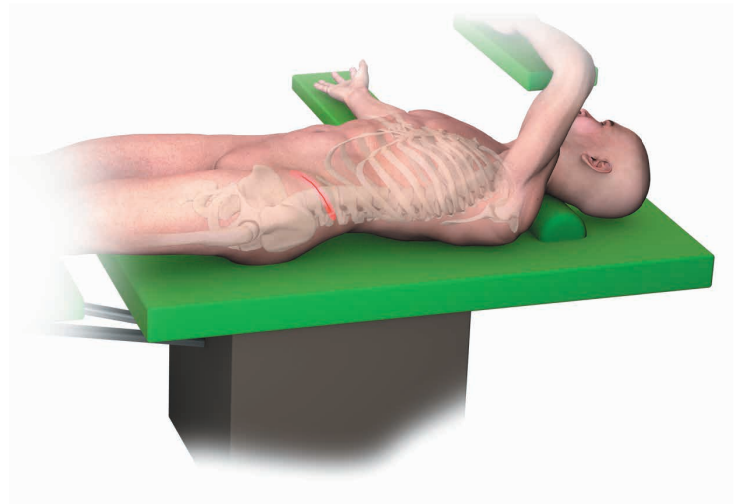
The anterior retroperitoneal approach is recommended for spine pathologies (*deformities, degenerations, fractures, tumours, infections*) situated between L2 and L5.

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.

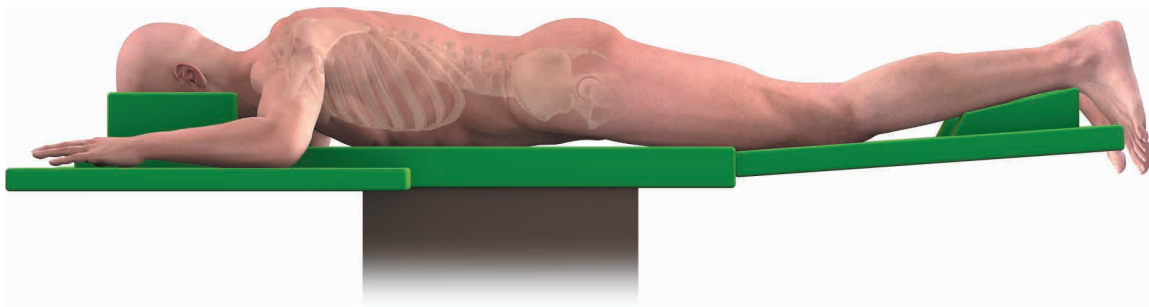
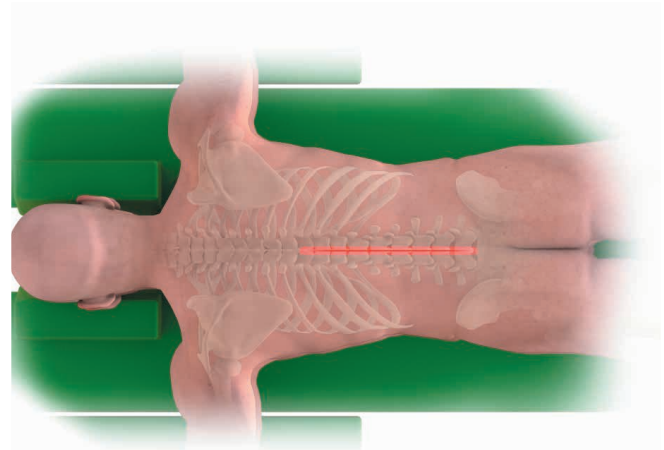
Indications

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 instability (*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 an 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.



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

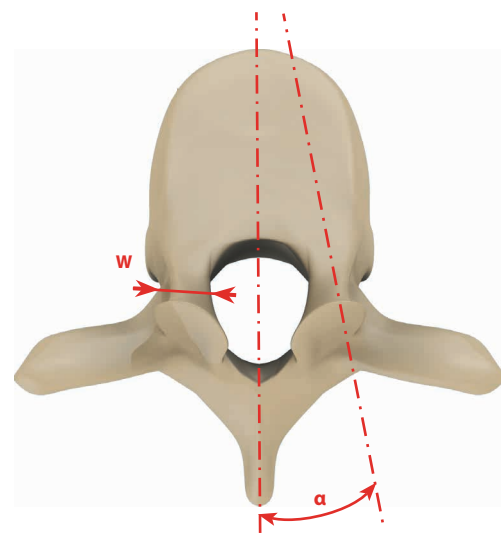
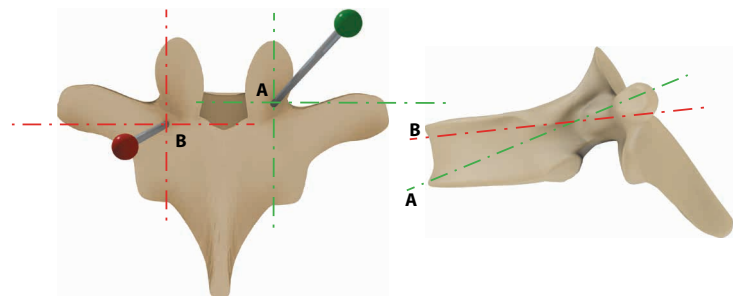
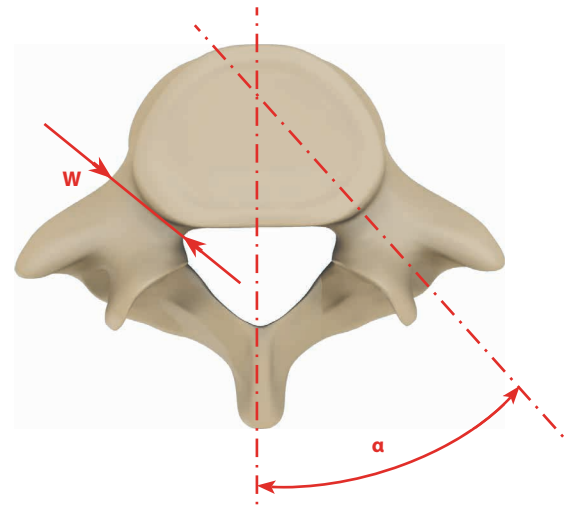
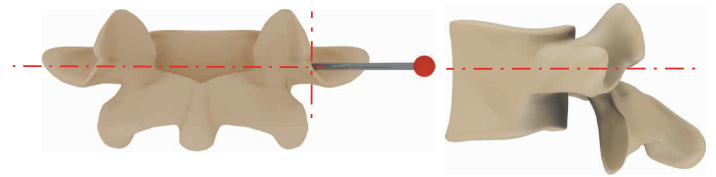
There are two alternative trajectories for insertion of screws through the thoracic vertebrae pedicles:

- 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.



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



40.8073.000

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.



40.8070.000



40.8071.000



40.8072.000

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]**).

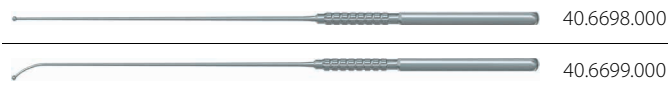
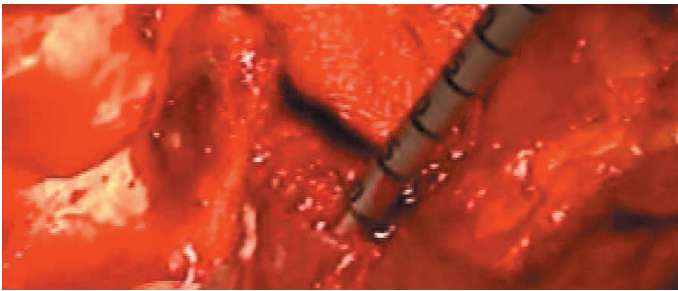
The instrument is inserted by means of delicate rotary-oscillatory movement.

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.



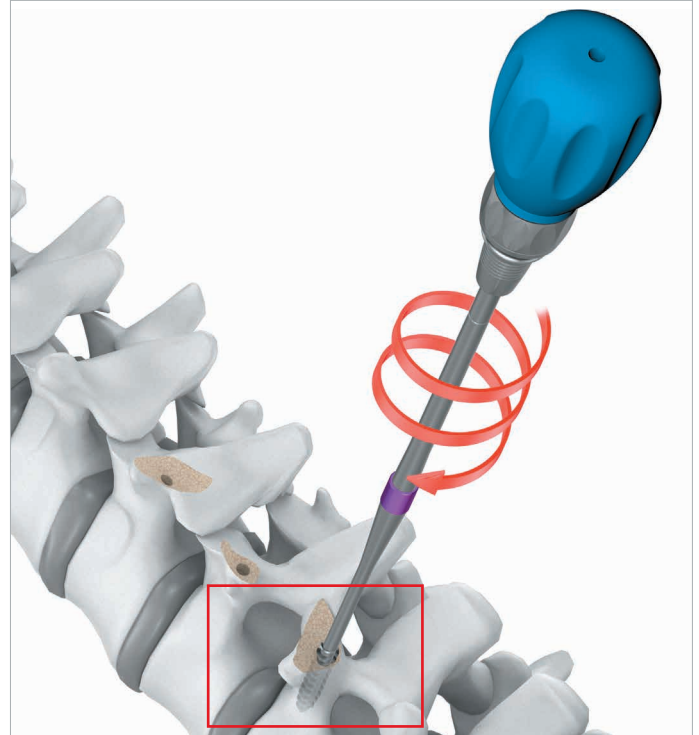
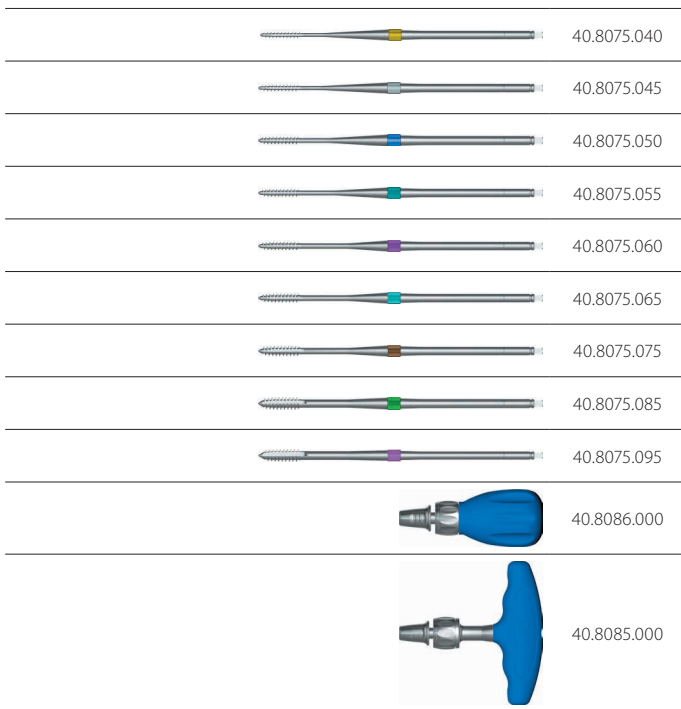
Trocar tip has marked depth indicators in five-millimeter increments to help determine the correct length of the transpedicular screw.

Identical procedure should be used while preparing the opening in the second pedicle.

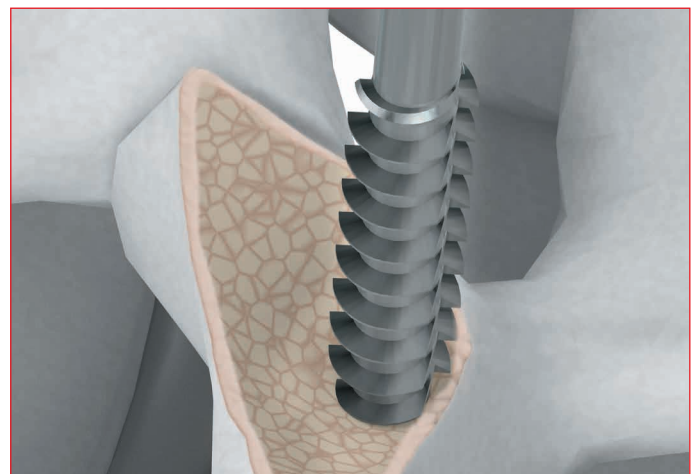


Prior to screw insertion, it is recommended to check the continuity of all walls of the vertebral arch pedicle with the help of the pedicle probe [40.6698] or [40.6699].

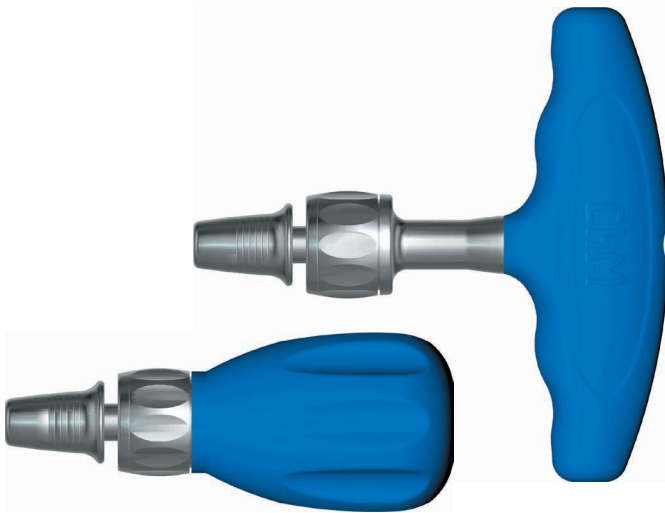


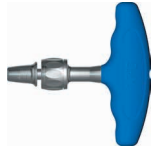





CHARSPINE2 screws are self-tapping, therefore there is no need to tap the vertebral arch pedicle. However, if tapping is clinically required, it is possible to use taps [40.8075.040÷40.8075.095] mounted on oval head ratchet handle [40.8086.000] or T-type ratchet handle [40.8085.000].



IV.7.2. INSERTION OF SCREWS

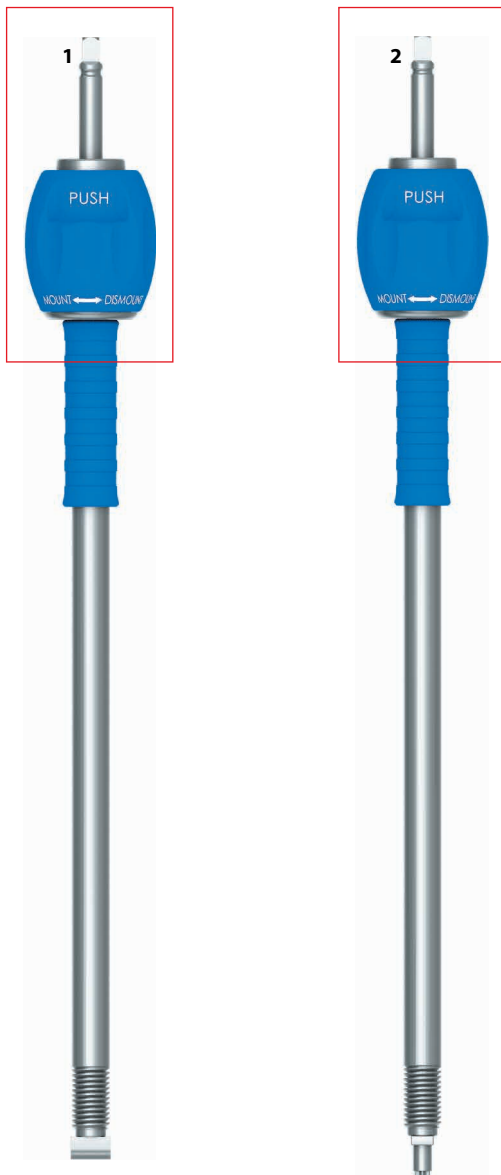


	40.8085.000
	40.8086.000
	40.8089.100
	40.8090.100

Wrenches for monoaxial [40.8090.100] and polyaxial screws [40.8089.100] 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.



Wrench for monoaxial screws [40.8089.100]

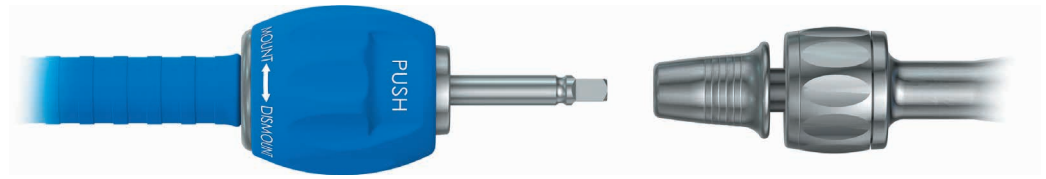
Wrench for polyaxial screws [40.8090.100]



Tips 1 and 2 of wrenches for screws are exchangeable. In order to disconnect the tip from the wrench [40.8090] or [40.8089], press and hold the PUSH and then remove the tip from the wrench sleeve.

The instrument set is equipped with additional tips for monoaxial [40.6145] and polyaxial [40.6146] screws. Therefore, e.g. two wrenches for polyaxial screws may be used by two operators simultaneously.

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 the case of monoaxial screws, a tip of wrench for monoaxial screws is to be used.



- in the case of polyaxial screws, a tip of wrench for polyaxial screws is to be used.



By turning the knob clockwise, tighten the threaded, external wrench sleeve all the way until the tip is completely seated at the bottom of the screw channel. Tightening direction is marked using arrow and MOUNT sign.

While tightening, with increasing resistance, the wrench knob automatically activates locking mechanism that will prevent the screw from being released from the wrench.





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.



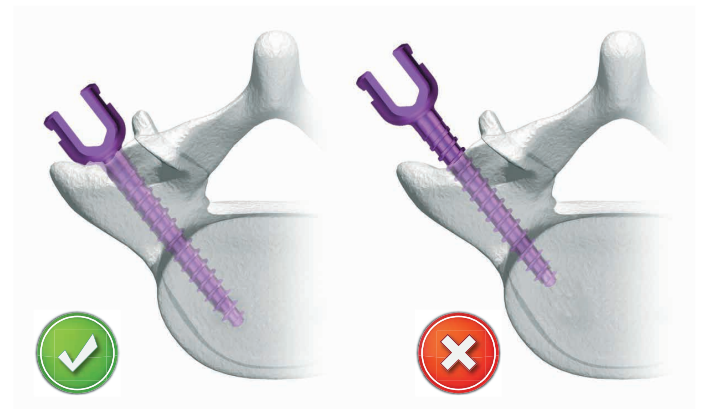
Remember that precise positioning of the screws is realised by screwing in, and not by screwing out.



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

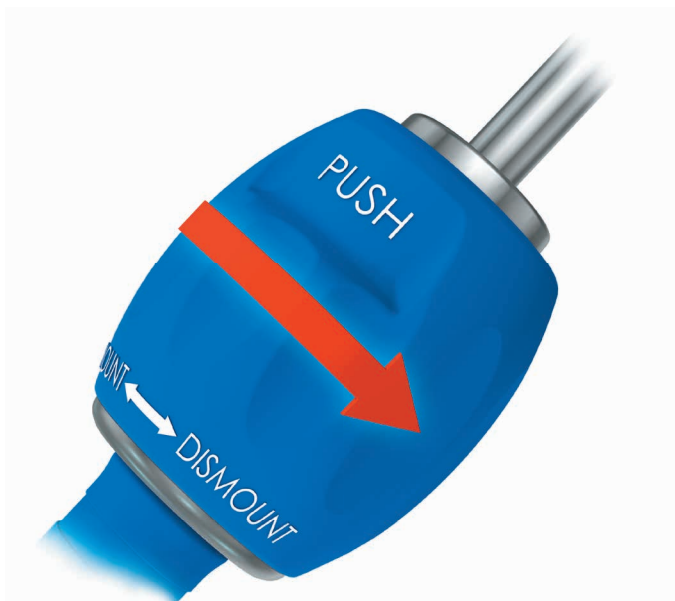


When screwing in, do not hold your hand on the oval handle of the wrench for screws, as this will cause the locking mechanism to disengage. If there is a need to use the other hand to hold the wrench, grasp the sleeve portion below the knob.



The core of the transpedicular screw is strengthened in the vicinity of its head.

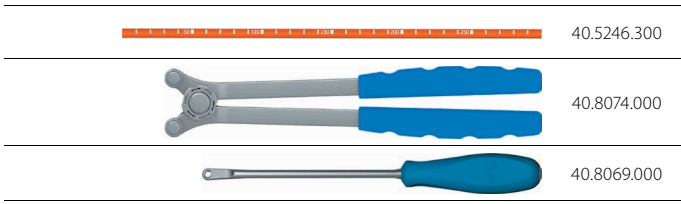
To reduce the potential risk of screw breakage, it is necessary to screw it all the way in so the whole thread is in the bone.



To remove the wrench from the screw, turn knob counter-clockwise as shown by the arrow and DISMOUNT sign.

The locking mechanism of the wrench will disengage automatically.

IV.7.3. ROD SHAPING

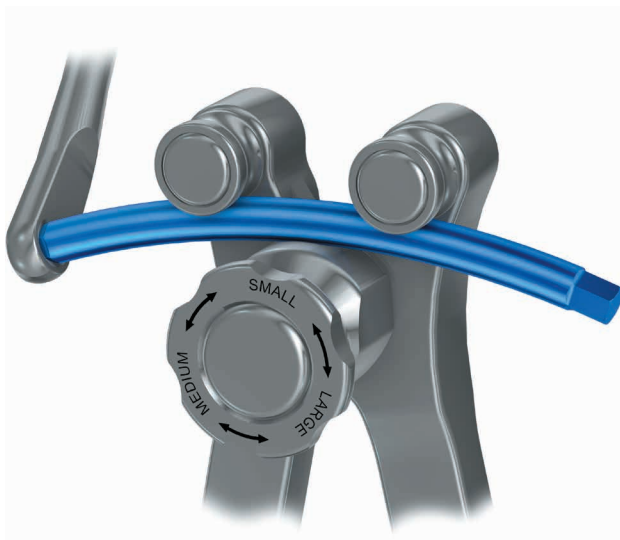


Having inserted the screws, a rod of appropriate length to the instrumented part of the spine should be selected.

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

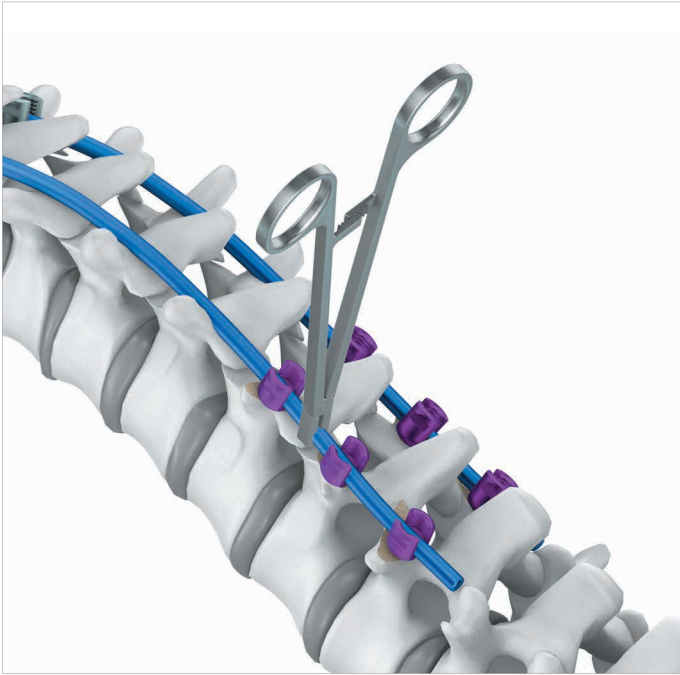
To achieve the desired spine curvature (e.g. lordosis or kyphosis), the rod should be appropriately shaped. Shaping is performed with the help of adjustable rod bender [40.8074.000]

To secure the rod against movement during shaping, eye wrench [40.8069.000] should be used.



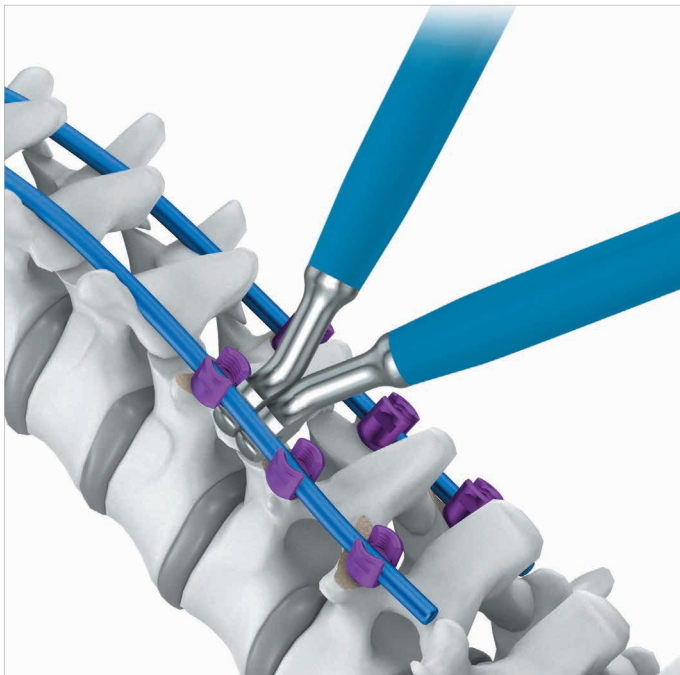
CHARSPINE2 system allows the usage of rods of two types of rigidity:

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



40.8109.000

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



40.8091.000



40.8092.000

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



40.5288.000

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.



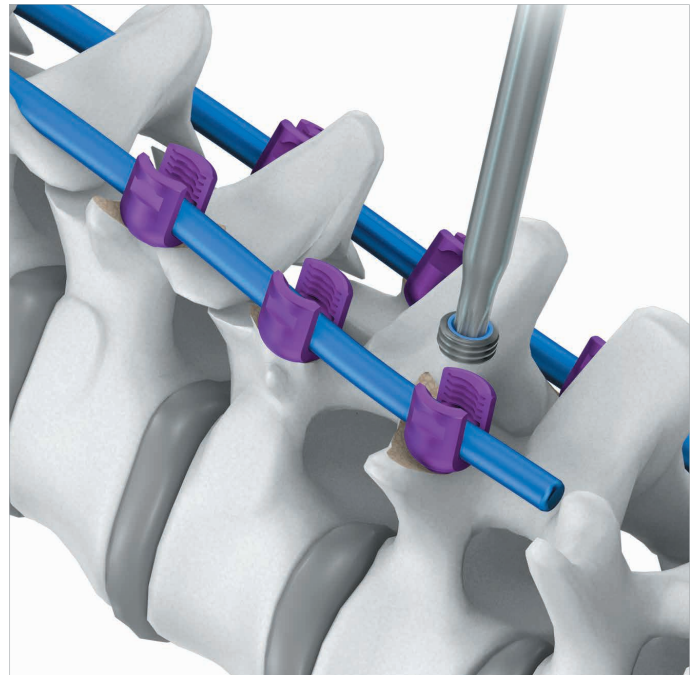
The locking screw may be mounted on the screwdriver tip only from the upper side of the screw (the locking screw design eliminates any errors related to the mounting).



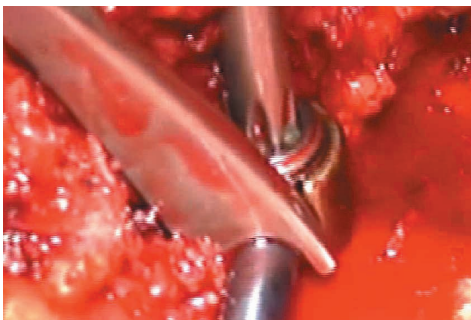
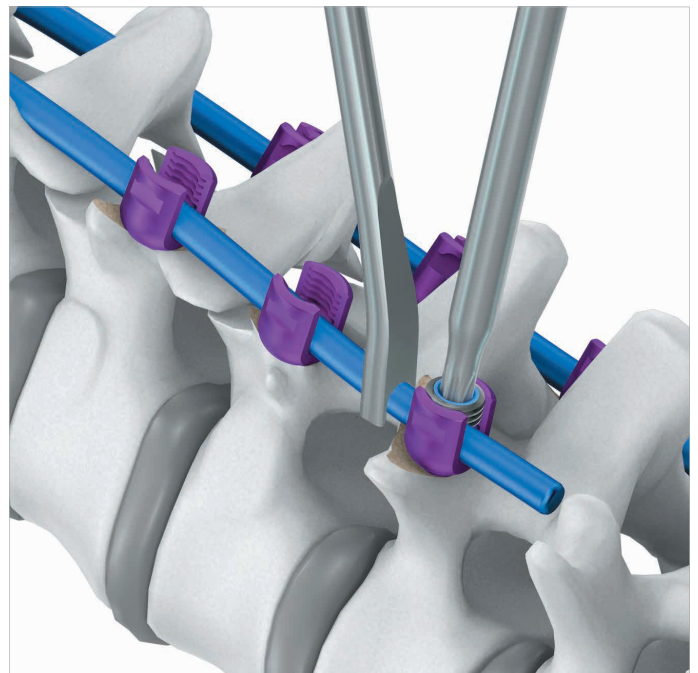
The upper surface of the screw is coloured to allow for easier identification.

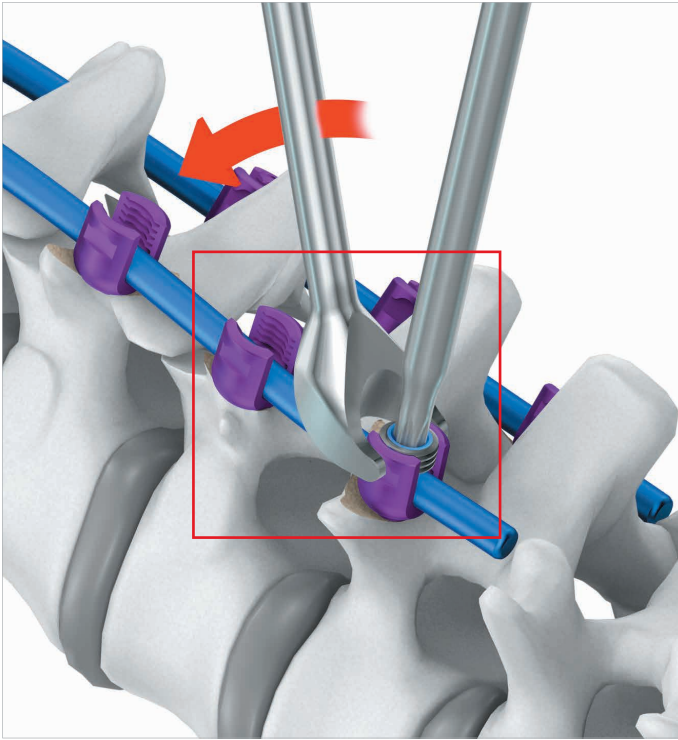


The locking screw is mounted on the tip of the screwdriver T30 **[40.8111.000]**, then it is inserted into the cut-out on the screw head and screwed in slightly in a clockwise direction, simultaneously gently pressing the rod to the screw cut-out bottom.



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

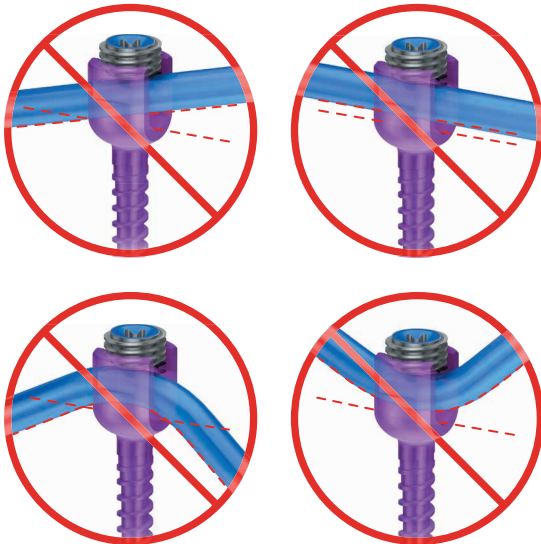
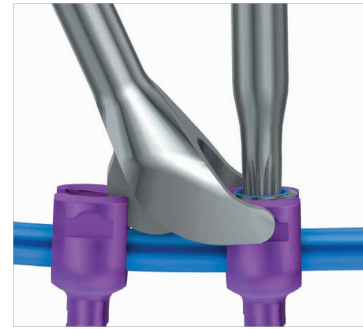




40.8100.000

To press the rod to the screw cutout bottom, it is possible to use also fork persuader **[40.8100.000]**.

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.



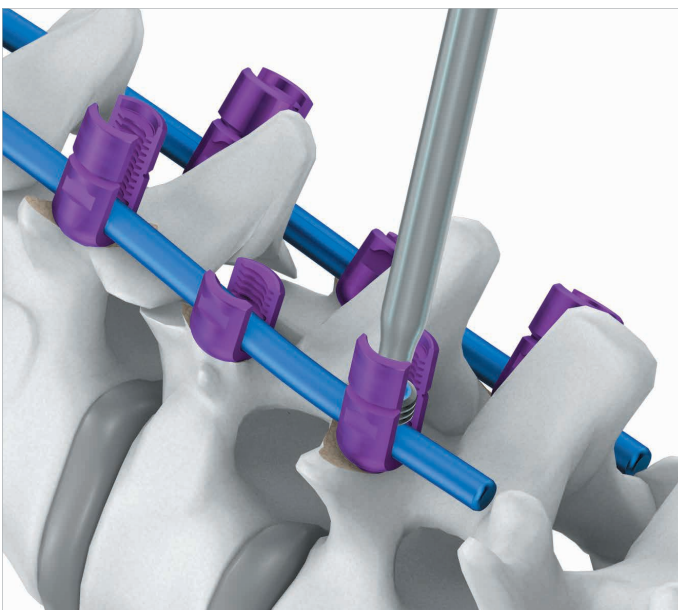
It is necessary to make sure that the rod and locking screw are completely mounted on the bottom of the screw head:

- the rod must be 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.

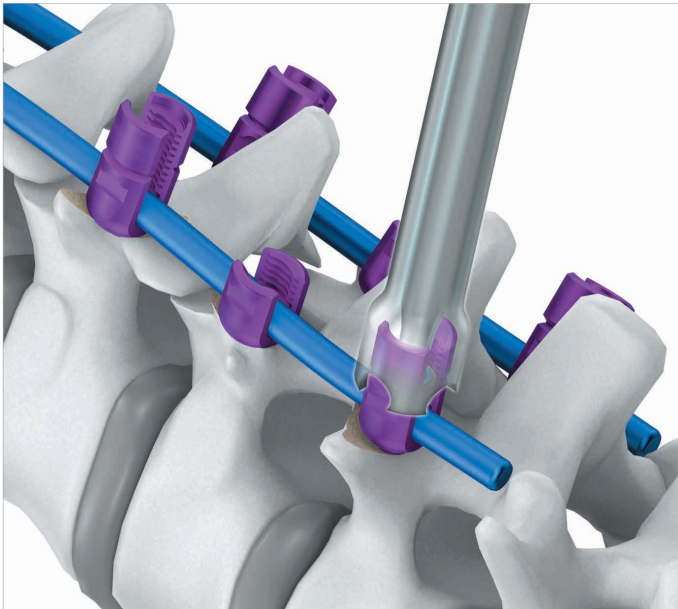


It is necessary to avoid the following:

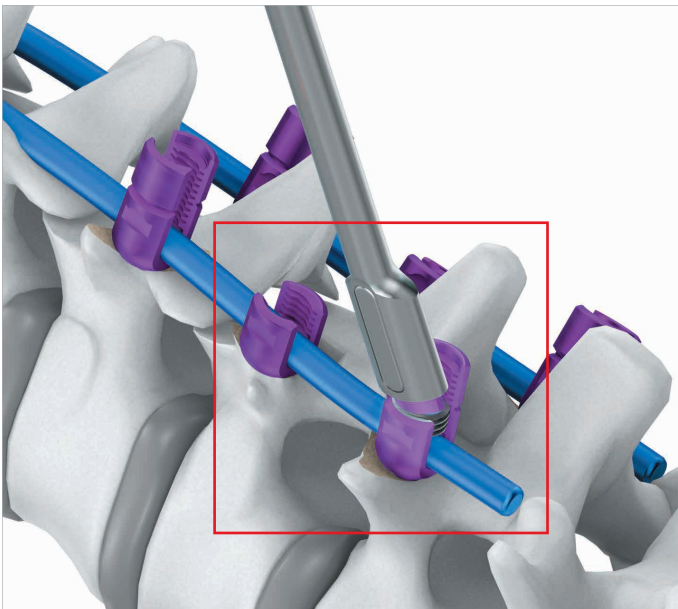
- the rod is not placed horizontally in the screw head,
- the rod is high and does not adhere to the bottom of the screw head cut-out,
- the screw is embedded in the place of rod bending (on the convexity or concavity of the arch).



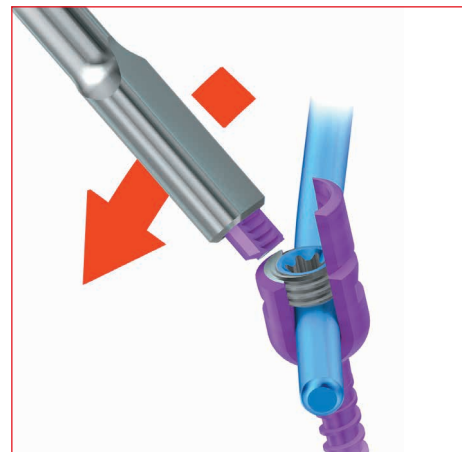
When the osteosynthesis covers more than three vertebrae, there is a risk that the rod may not fit to all screws cut-outs. In such case reduction screws are of help (with prolonged, breakable head arms). Alternative positioning of a few reduction screws allows for easy pressing the rod with a locking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



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].

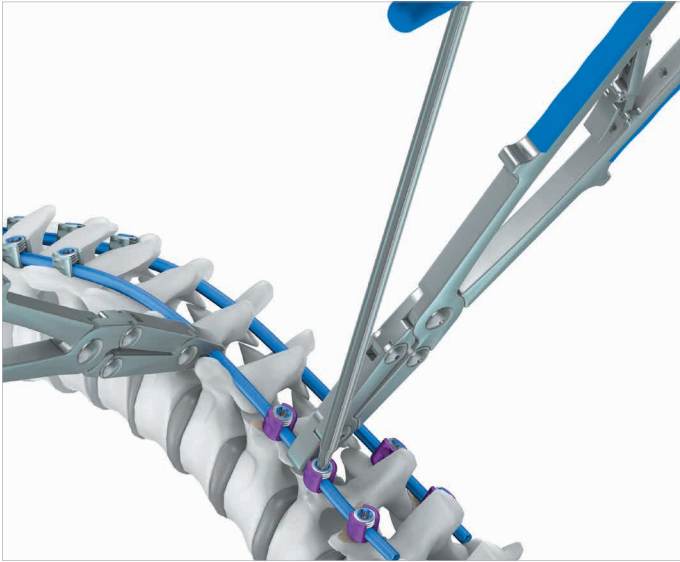


The abovementioned procedure may cause excessive reduction of screws (and vertebrae); to avoid this it is necessary to correct the rod bending in situ.



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 in any direction.

The use of uniplanar screws gives the possibility to tilt the head of the screw in the rostral-caudal direction, while ensuring medial-lateral stiffness.

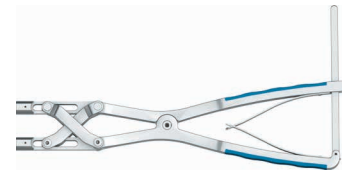


40.6202.000

It is possible to use the holding forceps [40.6202.000] 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.



40.8093.000



40.8094.000

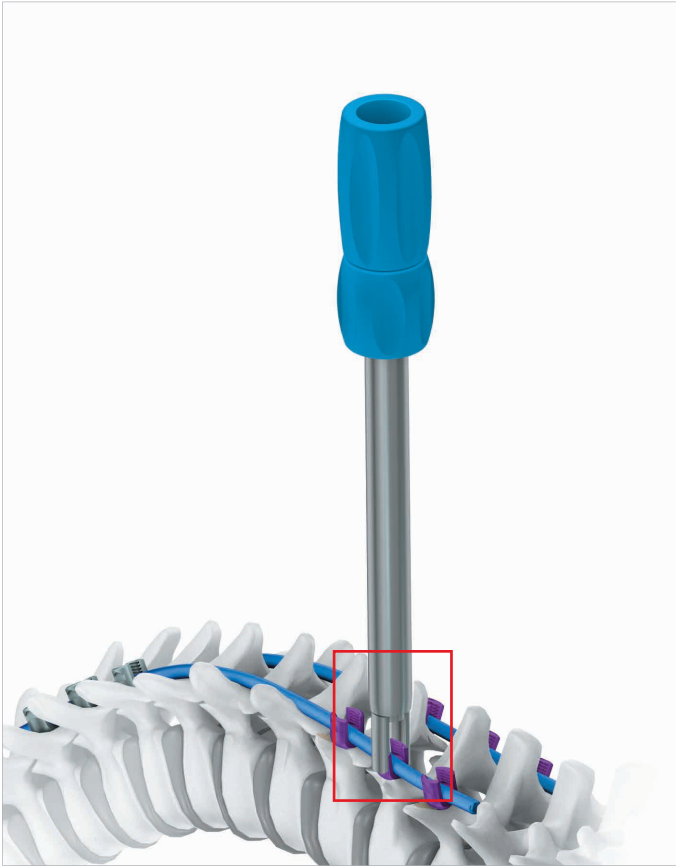


At this stage it is possible to perform:

- 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].



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



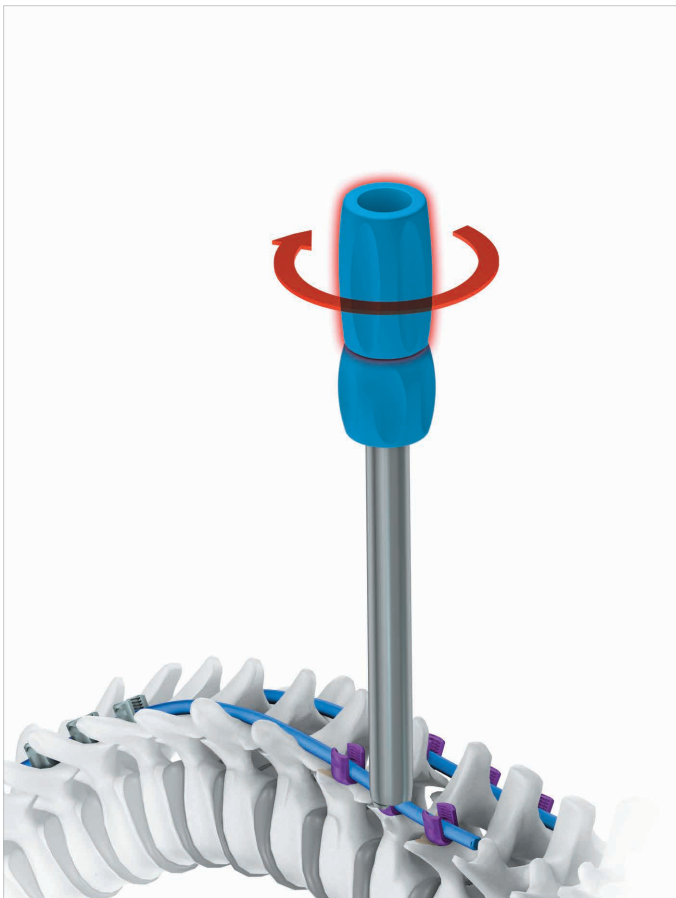
If more force is necessary to impact the rod into the bottom of the transpedicular screw cut-out, it is possible to use screw persuader [40.8096.100].



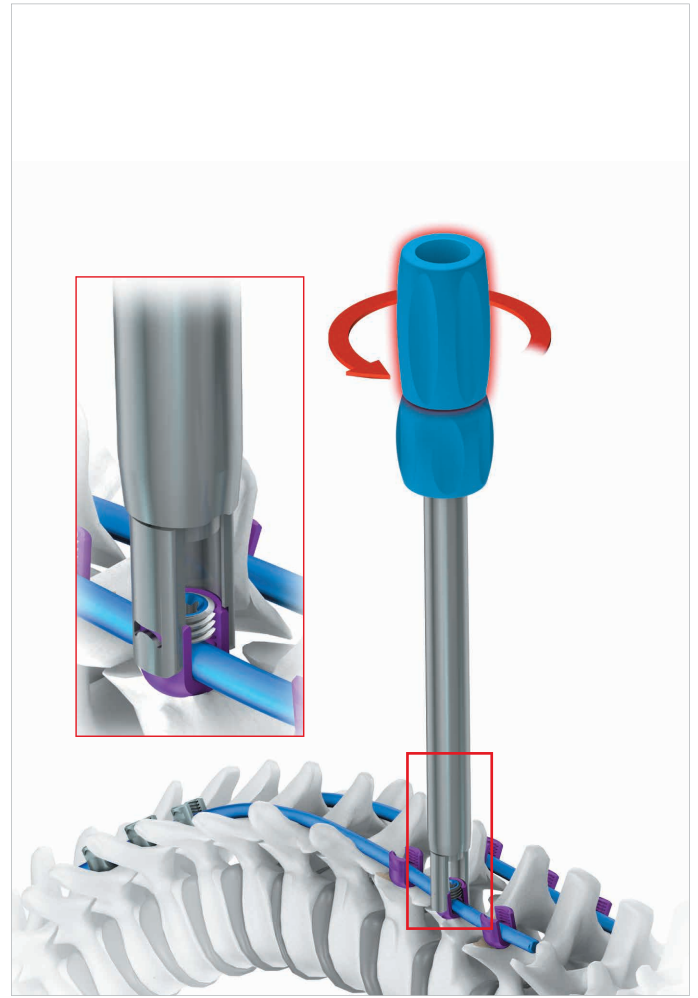
Prior to use, extend the clamping arms of the persuader as far as possible by turning the knob counterclockwise until a distinct resistance is felt.



Incompletely extended clamping arms of the persuader may cause the instrument to be improperly connected with the screw and may damage the device.

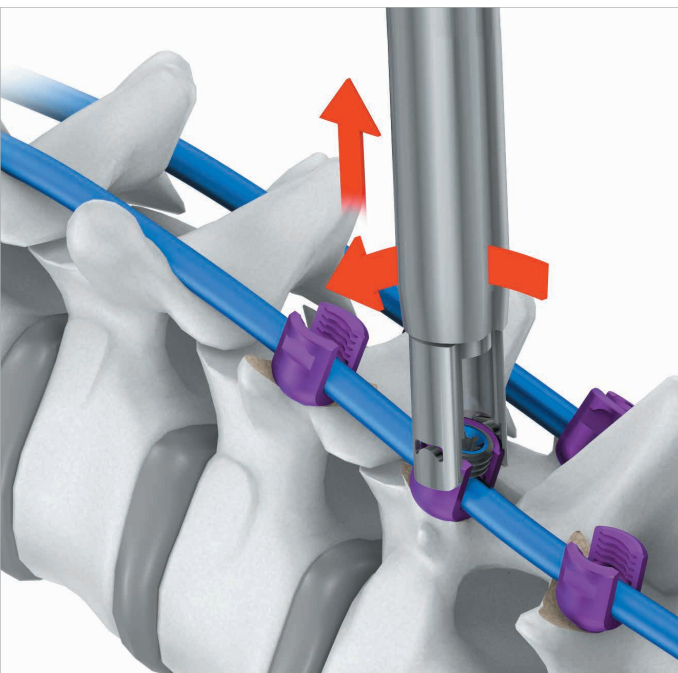


Then, by turning clockwise, the rod may be smoothly pushed down to the bottom of the screw.



Then turn the persuader knob counterclockwise to loosen the device and extend the clamping arms completely.

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.






The device is dismantled from the transpedicular screw by skewing the device in the rostral-caudal direction.



Incompletely extended clamping arms of the persuader may damage the device while dismantling.



	40.8087.000
	40.8084.000
	40.8095.000

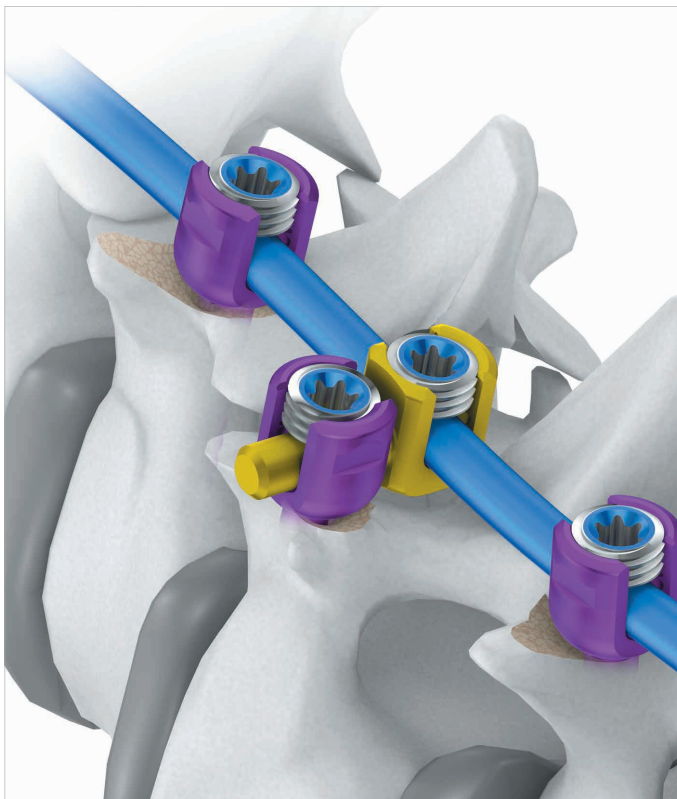
Having established the required vertebrae position, finally screw in the locking screws with the help of T-type torque handle 12Nm **[40.8087.000]** connected with screwdriver tip T30 **[40.8084.000]**.

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

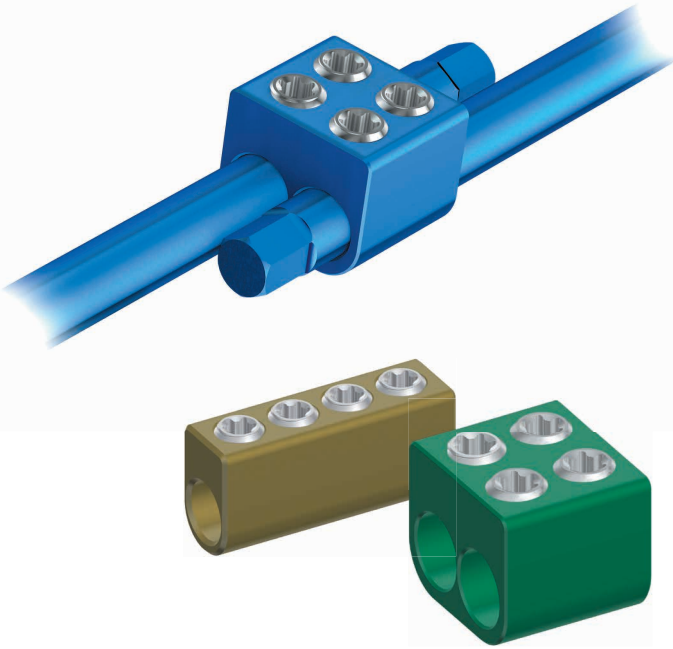
To eliminate the movement of rod-screws system while screwing in the locking elements use the counter wrench **[40.8095.000]**.



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.**

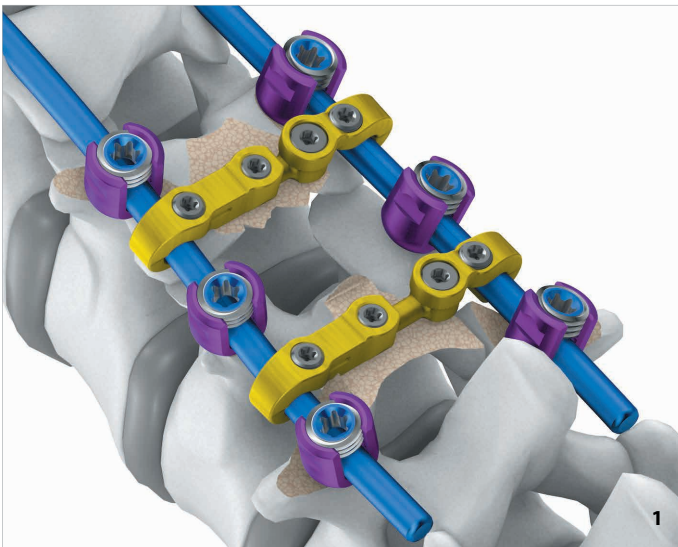


If it is needed to lengthen the fixation in lateral direction (*in relation to the main axis of stabilization*), it is possible to use a lateral connector. The connector is put on the main rod, then it is locked in a desired position (*after mounting the appropriate transpedicular screw*).



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

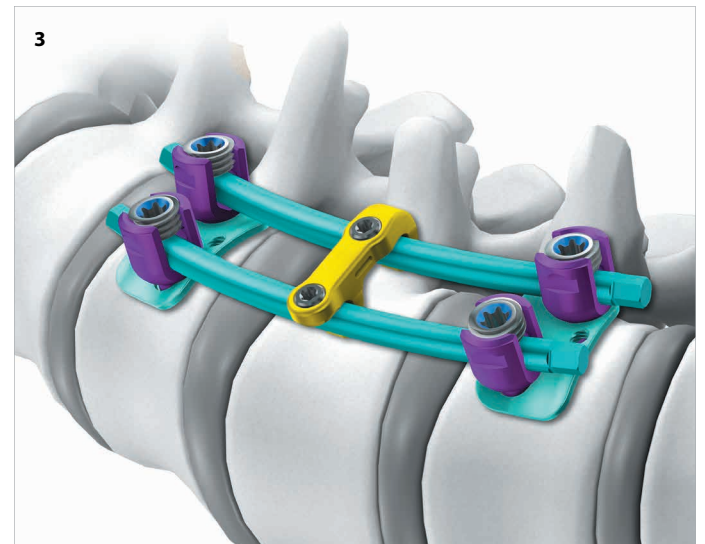
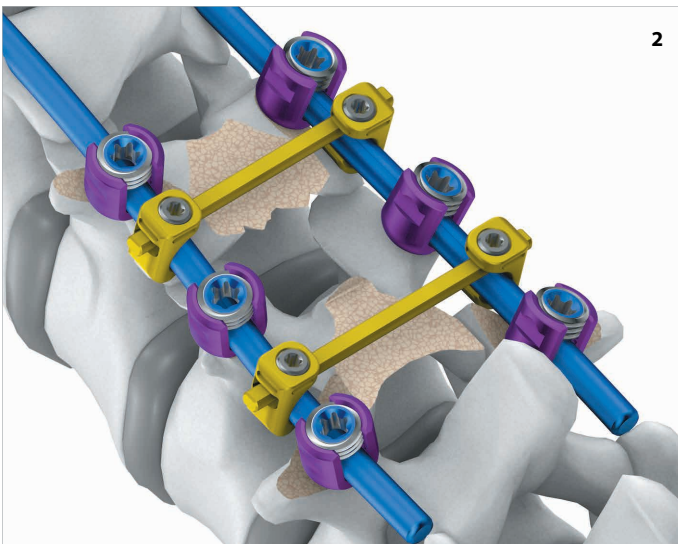
- crosswise connector,
- parallel connector.

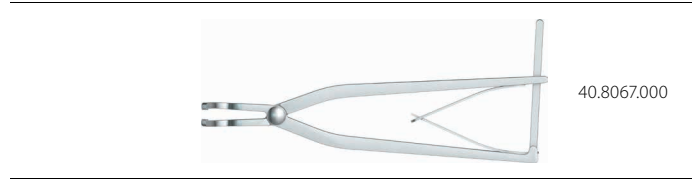


CHARSPINE2 allows for increase of rotational stability of the system by connecting two sides of rods with the help of a crosswise connector.

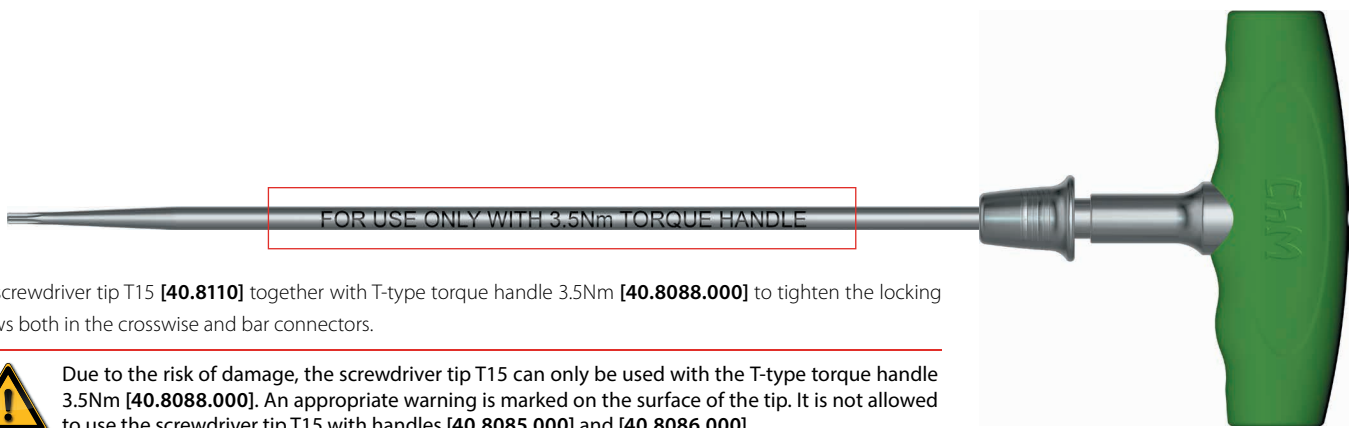
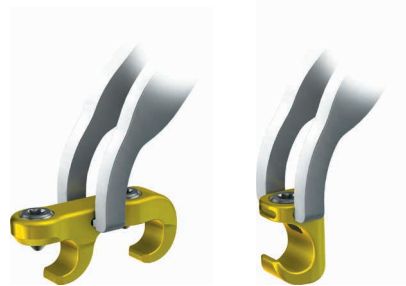
CHARSPINE2 offers three types of crosswise connectors:

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





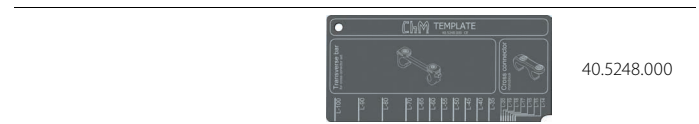
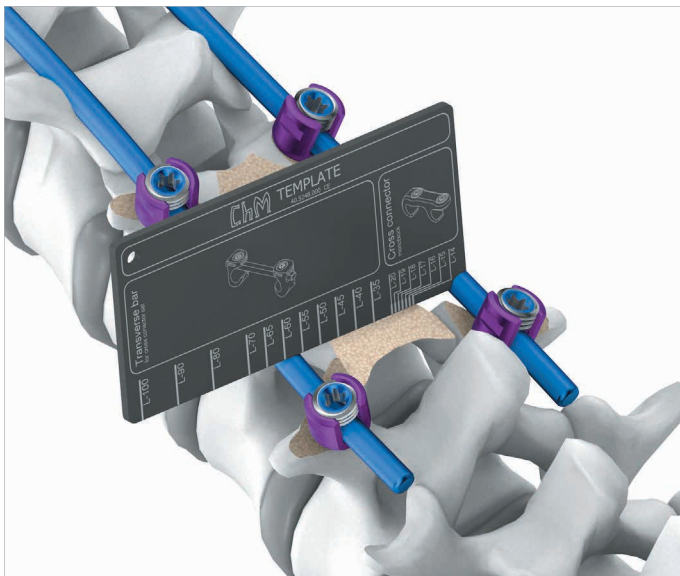
Crosswise connectors are inserted with the use of holder for crosswise connectors [40.8067.000]



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]

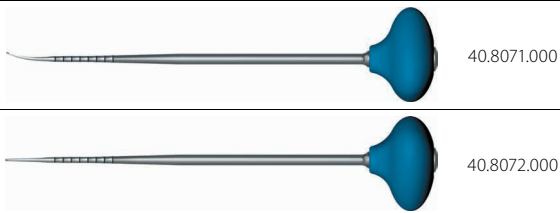
IV.8. INTRODUCTION OF POLYAXIAL SCREWS INTO THE PELVIS

Polyaxial screws for pelvis extend the lumbosacral stabilization and provide the fixation in the pelvic bone. The screw offers an increased, asymmetrical range of motion in one of the planes, facilitating screw-to-rod fixation.

The screw insertion hole is prepared using a universal [40.8071.000] or straight pedicular trocar [40.8072.000].



Pedicular trocar may not provide an opening corresponding to the full length of the screw for pelvis. This should be confirmed intraoperatively by X-Ray imaging.

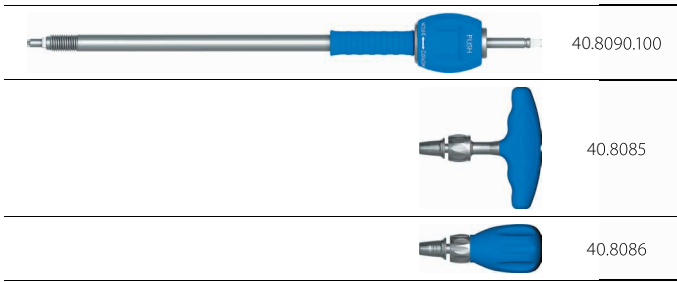
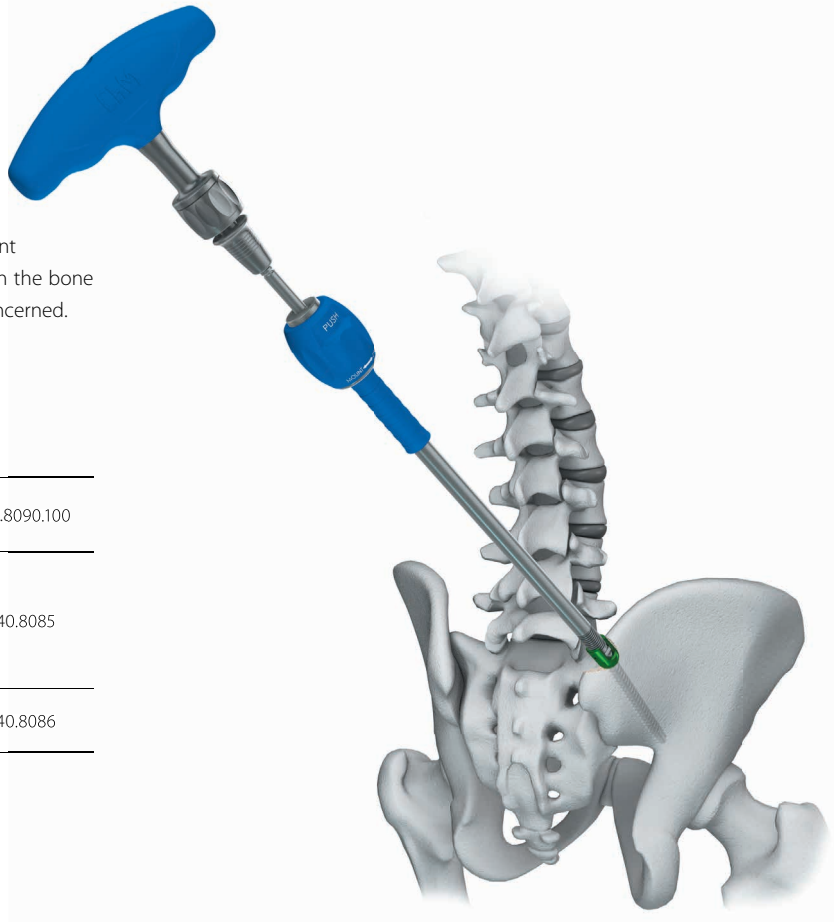


The optimum insertion trajectory of the screw for pelvis starts above the incisura ischiadica major and ends in the quadrilateral area of the pelvic bone above the linea glutea inferior. This trajectory ensures optimum fixation of the screw in the bone.

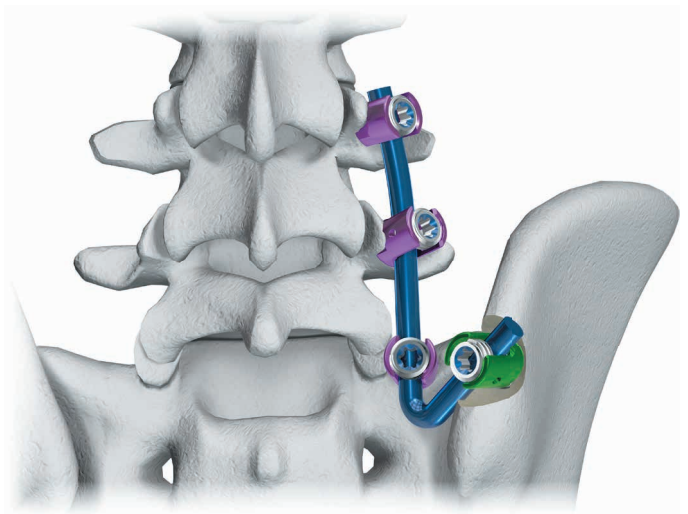


Polyaxial screw of a determined size is screwed into the prepared pelvic opening using the wrench for polyaxial screws **[40.8090.100]**, attached to the T-handle **[40.8085]** or oval handle **[40.8086]**.

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.

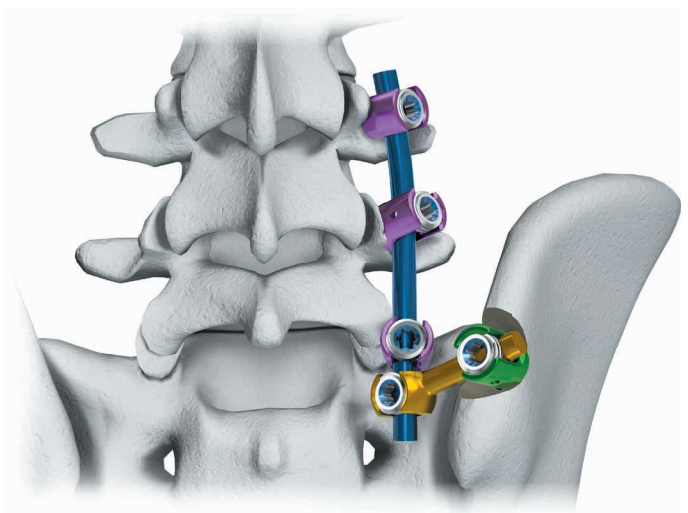


Most often the standard straight rod, e.g. **[3.3246.xxx]** is used for stabilization. The rod should be profiled so that the screw inserted into the S1 vertebra can be connected with the screw inserted into the pelvis. It is also possible to use factory profiled rod, e.g. **[3.3981.xxx]** should any difficulties with rod shaping appear.



A lateral connector, e.g. **[3.6283.xxx]** may also be used to connect the rod with the screw inserted into the pelvis.

Locking of the polyaxial screw for pelvis is performed in the same way as for standard polyaxial screws.



IV.9. HOOKS INSERTION

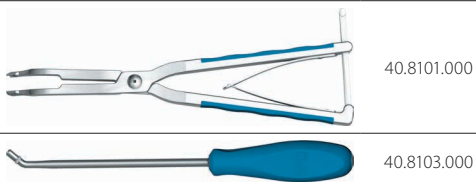
IV.9.1. PEDICLE HOOKS INSERTION

Pedicle hook is used for fixation of thoracic vertebrae and it is recommended for spine section between T10 and T11 vertebrae. Pedicle hook is always inserted in rostral direction, so its split blade leans on the vertebral arch pedicle.

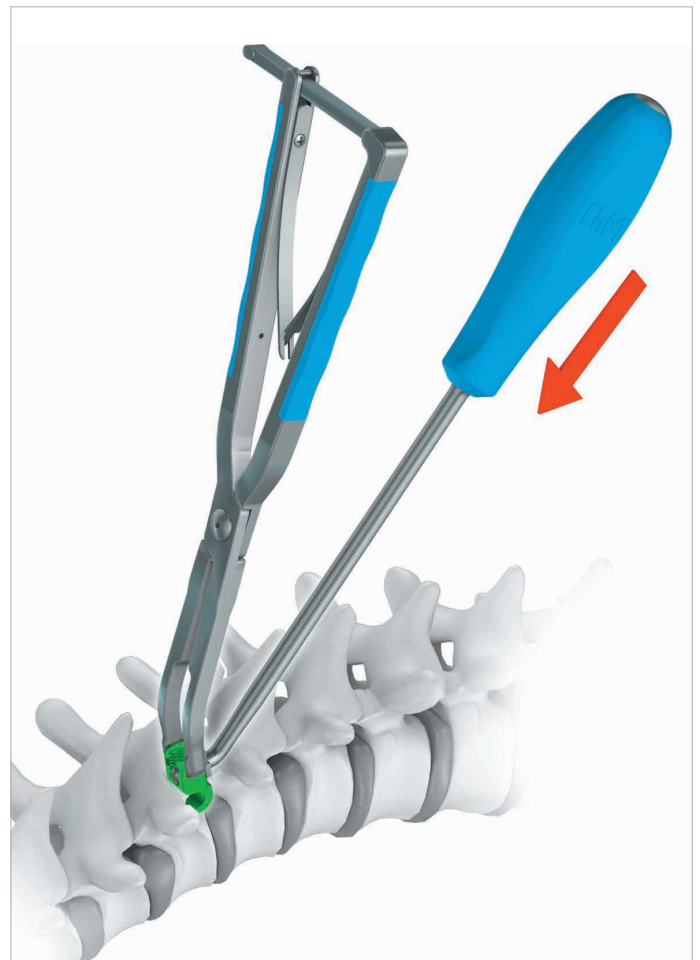
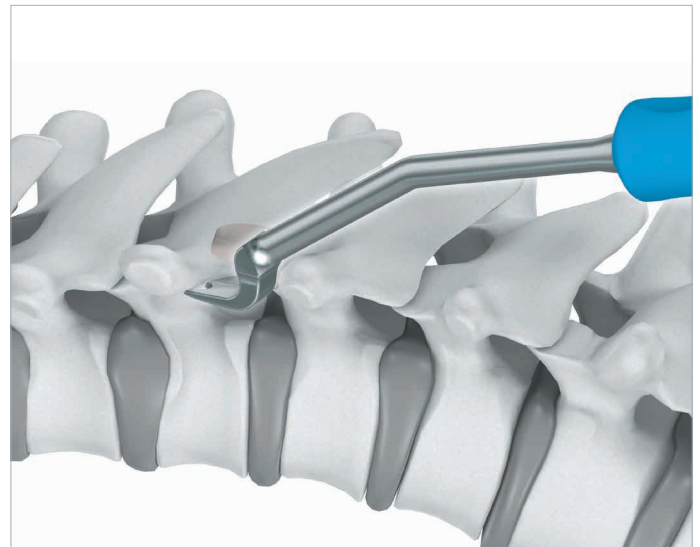
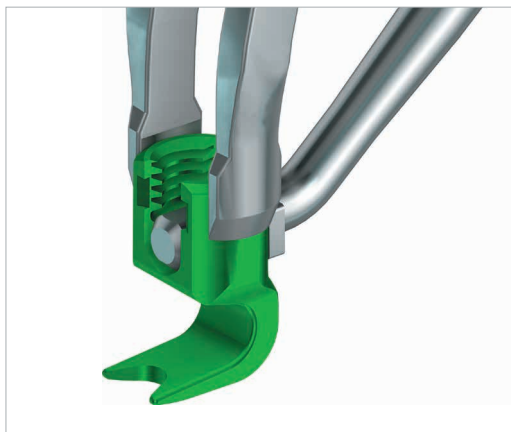
Place for pedicle hook insertion is prepared by a limited facetectomy. On the desired level, there are two incisions made on the surface of the inferior transverse process, enabling the access to the cartilage of the superior transverse process of the preceding vertebra.



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].

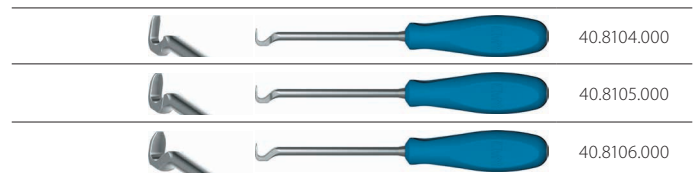
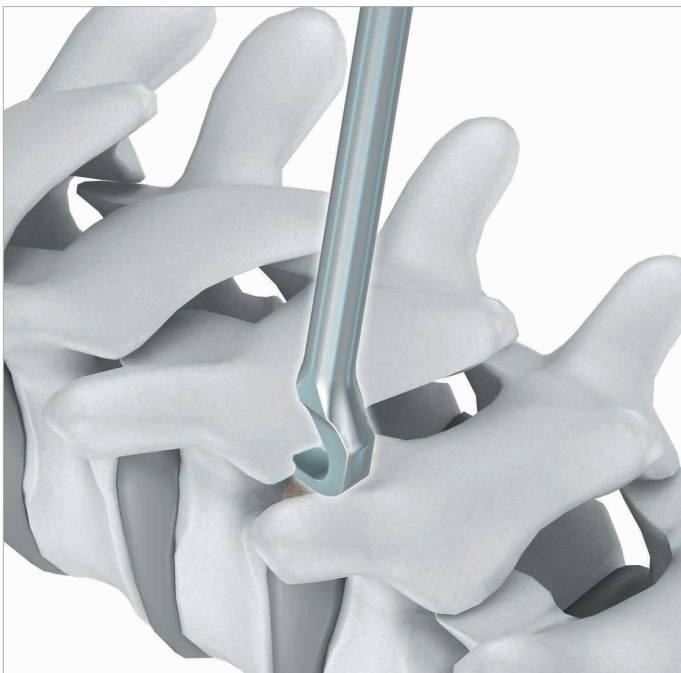


IV.9.2. INSERTION OF LAMINAR HOOKS

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.

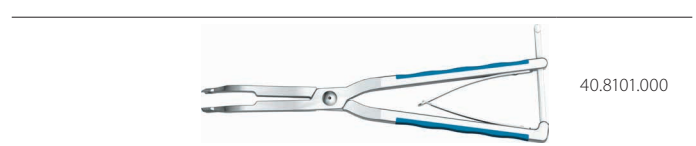
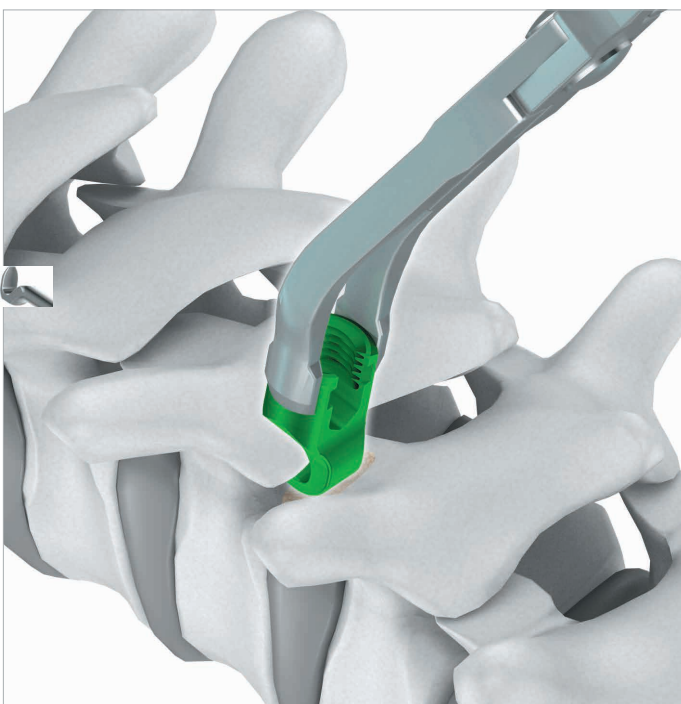
Laminar hook blade is inserted in space above the dura mater. To allow for appropriate passage of hook in spinal canal, a ligamentum flavum is removed and a limited laminectomy is performed.



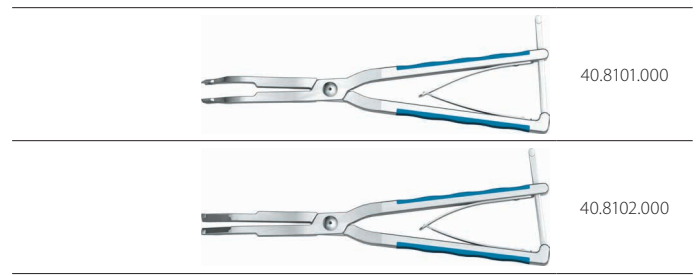
During the preparation of space for hooks the following raspatories for laminar hooks may be used:

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

Blade widths correspond to widths of laminar hooks available.



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

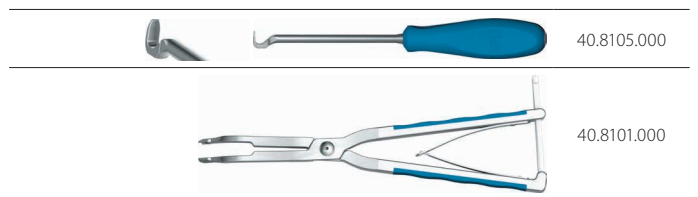
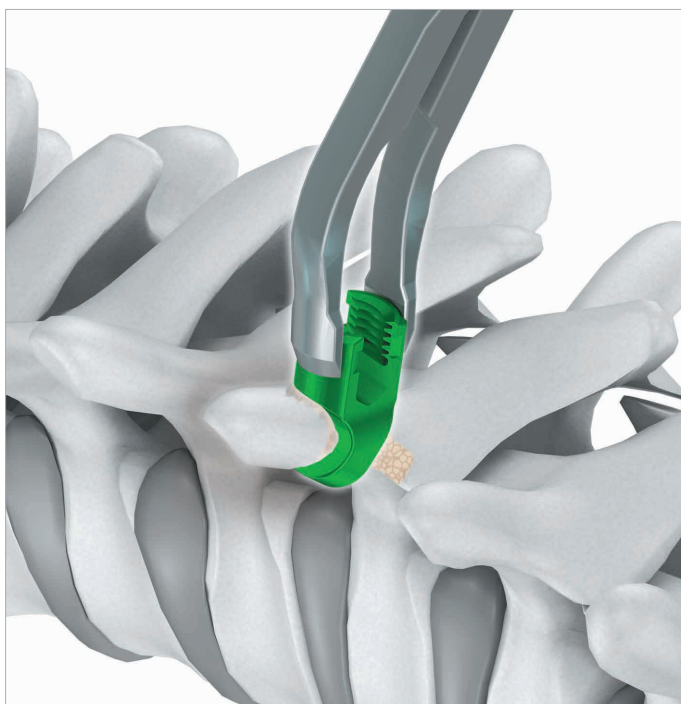


Alternatively, the selected hook may be mounted in jaws of lateral hook holder [40.8102.000], e.g. in situation when anatomical structure hinders the use of a holder [40.8101.000].

IV.9.3. 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 inserted 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 front surface of the transverse process is prepared with the use of raspator 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.

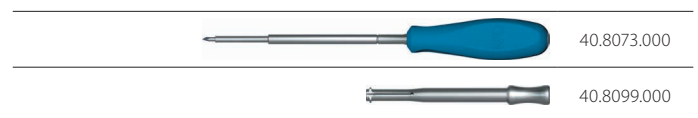
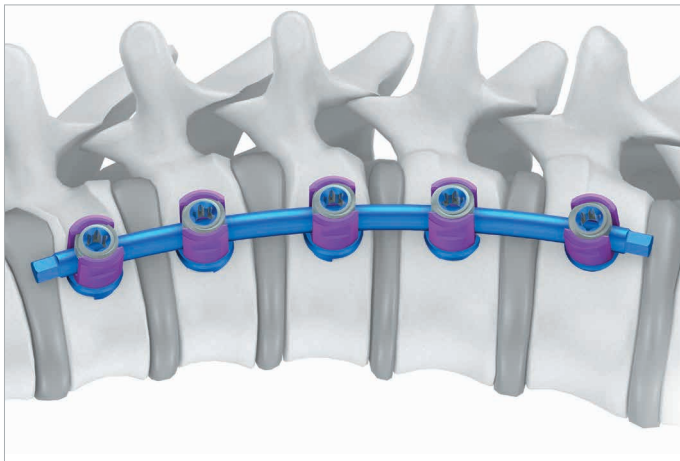
IV.10. INSERTION OF SCREWS-ANTEROLATERAL APPROACH

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*).

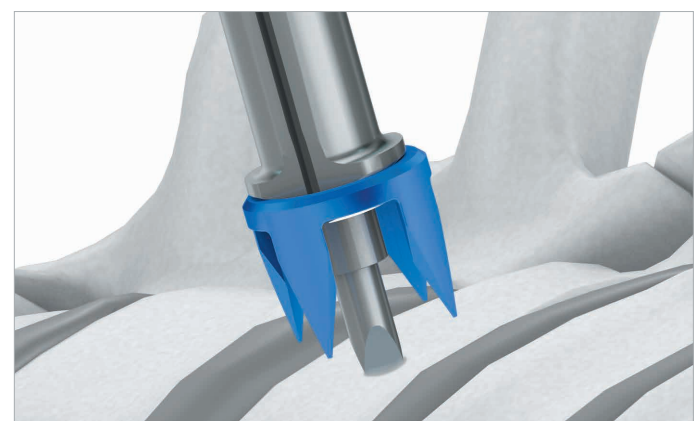
It is recommended to use a dual-rod system because of a higher strength and stability. However, during the treatment of thoracic scolioses the insertion of two screws into each vertebral pedicle may be anatomically difficult, especially in upper and medial thoracic vertebrae. In such case a single-rod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

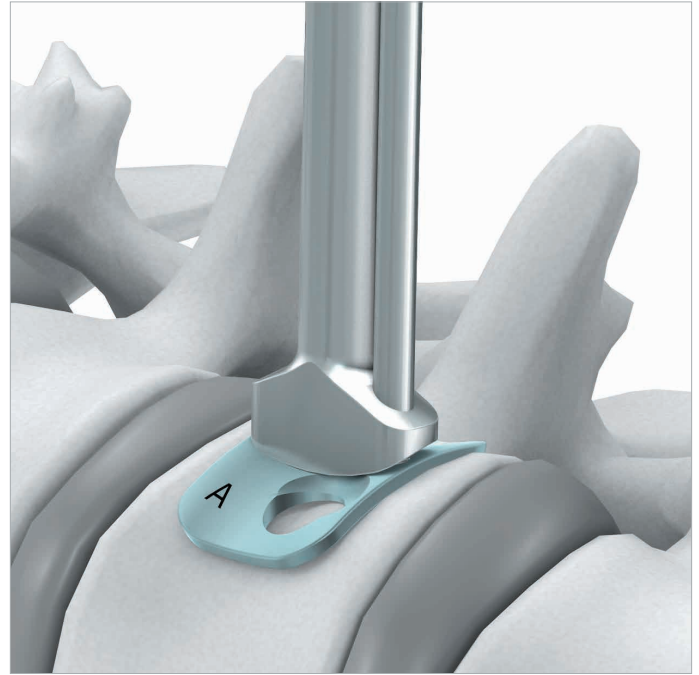
The implantation begins with the insertion of single- and double-hole staples (*depending on the instrumented spine level*).

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 [**40.8099.000**] attached.

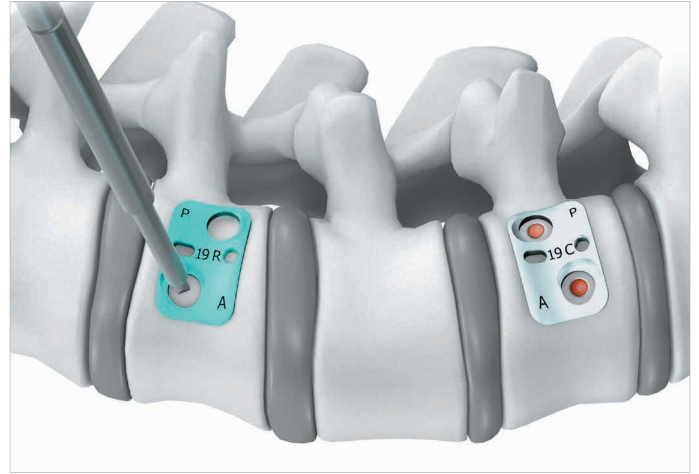




Double-hole staples are inserted and positioned with the help of an impactor for staples [40.8098.000].



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.

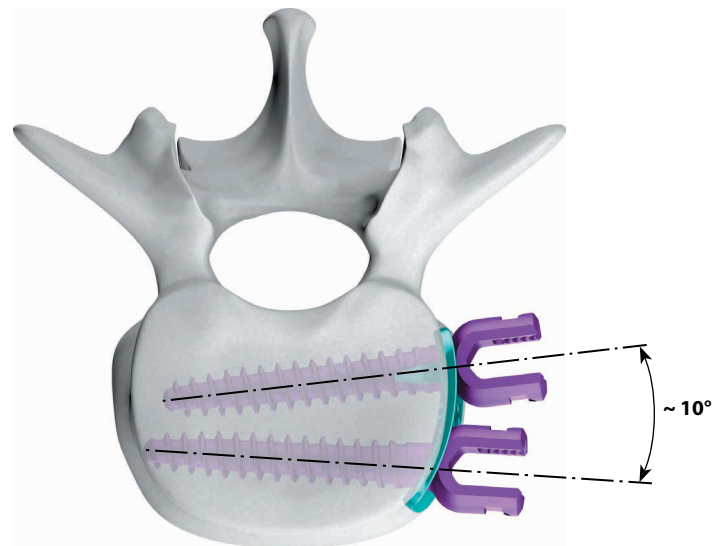


Screw insertion point should be prepared with the help of a trocar [40.8073.000] which penetrates the cortex of the vertebral body in the center of the staple hole.

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.



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

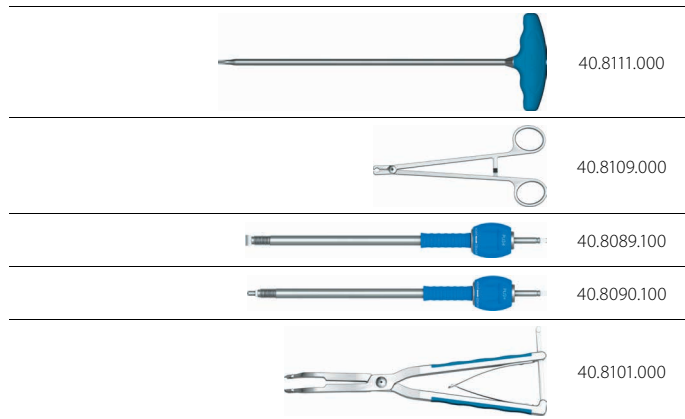


The insertion and locking of screws is performed in the same manner as already described in chapter INSERTION OF SCREWS - ANTERIOR APPROACH

IV.11. 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 **[40.8089.100]**, wrench for polyaxial screws **[40.8090.100]** or hook holder **[40.8101.000]**.





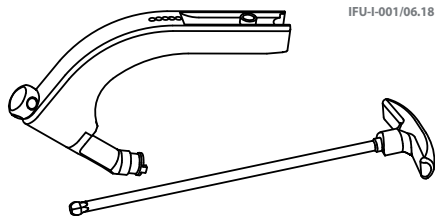
REUSABLE ORTHOPAEDIC AND SURGICAL INSTRUMENTS

GB

ChM

CE

Manufacturer: ChM sp. z o.o.
Lewickie 3b, 16-061 Juchnowiec K., Poland
tel.: +48 85 86 86 100 fax: +48 85 86 86 101
e-mail: chm@chm.eu www.chm.eu



IFU-I-001/06.18

INSTRUCTIONS FOR USE REUSABLE ORTHOPAEDIC AND SURGICAL INSTRUMENTS

1 INDICATIONS

1. Surgical and orthopaedic instruments are intended for use only by skilled and trained medical professionals who are familiar with their use and application.

2 DESCRIPTION

1. The unit package contains one piece of the product in non-sterile condition. Clear plastic bags are a typical packaging material. The products may also be supplied as a complete set (arranged on palettes and placed into specially designed sterilization containers). This Instructions For Use is attached both to the unit packages and the sets.
2. The package is equipped with the product label. The label (as a primary label) contains, among others:
1) Logo ChM and the address of the manufacturer.
2) Catalogue number (REF), e.g.: 40.XXXXX.XXX, and device name and size.
3) Production batch number (LOT), e.g.: XXXXXXX.
4) NON-STERILE sign - indicates non-sterile product.
5) Information symbols (described in the footer of this Instructions For Use).
6) CE conformity mark.
3. Depending on the size or type of the product, the following information may be marked on its surface: manufacturer's logo, production batch no. (LOT), catalogue no. (REF), type of material and device size.

3 MATERIALS

1. For the production of instruments, ChM sp. z o.o. uses mainly: steel, aluminum alloys and plastics, approved for use in surgical instruments and in accordance with applicable procedures.
2. Instruments are produced of corrosion-resistant steel. The protective layer (passive layer) against corrosion is formed on the surface of the device due to high content of chromium.
3. Devices produced of aluminum are mainly stands, palettes, cassettes and some parts of instruments such as e.g. handles. The protective oxide layer which may be dyed or stained in natural colour (silver-grey) is formed on the aluminum as an effect of electrochemical treatment of its surface.
4. Devices made of aluminum with processed layer have good corrosion resistance. However, the contact with strong alkaline cleaning and disinfecting agents, solutions containing iodine or some metal salts, due to chemical interference with the processed aluminum surface, shall be avoided.
5. Devices produced of plastics are mainly stands, palettes, cassettes and some parts of instruments such as e.g. handles. Plastics used in the manufacture of instruments are mainly: PPSU (Polysulfone), PEEK (Polyetheretherketone), teflon (PTFE - Polytetrafluoroethylene) and silicone. 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 a pH value from 4 to 10.8.
6. Steel surgical instruments with a hardened insert are more durable than steel products. The advantage of the product is the sintered carbide insert placed in the working part of the instrument. This insert is characterized by great hardness and abrasion resistance.
7. If the material of the device cannot be specified, please contact ChM sp. z o.o. representative.

4 WARNINGS AND PRECAUTIONS

1. Instruments are intended for use only by skilled and trained medical professionals who are familiar with their use and application.
2. Improper, careless and inconsistent with the recommendations provided below handling of the instruments can lead to their chemical, electrochemical or mechanical damage which can adversely affect corrosion resistance and shorten the service life of the devices.
3. 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 consequence, damage to the instrument.
4. The surgeon should be familiar with all components of the device before use and should personally verify if all components and instruments are present before the surgery begins.
5. Before the procedure begins, all instruments should be carefully inspected for their condition and proper functioning. They should be undamaged and without any signs of corrosion. Blades and cutting edges should be sharp and undamaged. Damaged or corroded instruments should be immediately replaced. The use of bent, damaged or corroded instruments is not allowed.
6. Tissue structures close to the operative site must be protected.
7. Collision of the instrument with metal operating equipment, retractor or other device may cause damage that necessitates intraoperative replacement of that instrument.
8. Do not apply excessive force when using the instrument - it may lead to its permanent damage and, in consequence, to mal-function of the device.
9. Instruments are subject to constant wear processes. While rare, intraoperative fracture or breakage of the instrument can occur. Instruments which have been subjected to prolonged use or excessive forces are more susceptible to fractures, depending on care taken during surgery and the number of procedures performed. Should breakage occur, the instrument parts must be removed and disposed of immediately in accordance with valid facility procedures.
10. In order to confirm the removal of all undesired metal fragments from the surgical field, intraoperative X-ray examination is recommended.
11. 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.
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.
13. Instrument which had contact with tissues or body fluids of another patient cannot be re-used prior to its reprocessing due to a potential risk of cross-infection caused by viruses, bacteria and prions.
14. Middle and working part of the surgical devices with hardened insert shall be used during the surgical procedure. Improper or inconsistent with the intended purpose usage of the product may lead to damage of the working part e.g. damage to the inserts.

5 CLEANING, DISINFECTION, STERILIZATION

1. Prior to use of a non-sterile device, the following rules apply:
1) The device must undergo cleaning, disinfection and sterilization procedures.
2) Effective cleaning is a complicated procedure depending on the following factors: the quality of water, the type and the quantity of used detergent, the technique of cleaning (manual, automated), the proper rinsing and drying, the proper preparation of the device, the time, the temperature and carefulness of the person conducting this process, etc.
3) The hospital facility remains responsible for the effectiveness of the conducted cleaning, packaging and sterilization processes with the use of existing equipment, materials and properly trained personnel.
2. Preparation at the place of use.
1) Immediately after use, remove from instrument blood and other contaminants with disposable cloth or paper towels. Additionally, it is recommended to rinse the instrument under running water or to place it in the aqueous disinfectant solution. Do not let blood, tissues, body fluids or other biological impurities dry out on the surface of the device.
2) In order to prevent blood and debris from drying out on the instrument surface, transport the product to the

processing area in a closed container or covered with a damp cloth.
3) In order to avoid contamination during transportation, the dirty instruments should be separated from the clean ones.

3) Preparation for washing and disinfection (for all methods).

- 1) The used instruments should be reprocessed as soon as possible.
- 2) If the instrument can be disassembled, it must be done before cleaning processes.
- 3) Rinse under running water and remove surface debris using a disposable cloth, paper towel or plastic brushes (nylon brushes are recommended). Particular attention should be paid to openings and places difficult to be cleaned. Very dirty devices should be soaked in an aqueous solution of a detergent or a washing-disinfecting agent, e.g. neodisher® MedClean forte, at temperature of 40+/- 2°C and pH of 10.4-10.8 (follow the information contained in the instructions prepared by the manufacturer of the agent, in respect of temperature, concentration, exposure time and water quality).

4) CAUTION: It is forbidden to use brushes made of metal, bristles or materials which could damage the product.

4) Cleaning and disinfection process.

1) This Instructions for Use describes two ChM-approved cleaning and disinfection methods: manual with ultrasound cleaning and automated method. It is recommended to use automated cleaning and disinfection procedures (in a washer-disinfector).
2) The chosen washing and disinfecting agents must be suitable and approved for use with medical devices. It is important to follow the instructions and restrictions specified by the producer of those cleaning agents. It is recommended to use aqueous solutions of washing-disinfecting agents with a pH value between 10.4 and 10.8. ChM used the following materials during the validation process of the described recommendations for cleaning and disinfection. It is allowed to use other materials than those listed below which may also give a comparable effect:

- a) detergent - Dr. Weigert (producer) neodisher® MedClean forte (name of the detergent);
 - b) disinfectant - Dr. Weigert (producer) neodisher® Septo Active (name of disinfectant).
- 3) To prevent product damage (pitting, rust, discoloration), do not use aggressive cleaning agents (NaOH, NaOCl), saline solutions and unsuitable cleaning agents.
4) Where possible, it is recommended to use demineralized water to avoid the formation of spots and stains caused by chlorides and other compounds present in ordinary water.
5) Manual with ultrasound cleaning.
a) Equipment and materials: a device for ultrasound cleaning, soft, lint-free cloths, plastic brushes, syringes, aqueous solutions of cleaning agent.
b) Manual cleaning: Initial manual cleaning must be performed prior to ultrasound cleaning.
c) Rinse under running water until the product is visually clean. Use plastic brushes to remove heavy or large debris.
d) Soak the product for at least 10 minutes in an aqueous solution of a detergent at temperature of 40+/- 2°C and pH of 10.4-10.8 (follow the information contained in the instructions prepared by the manufacturer of the agent, in respect of temperature, concentration, exposure time and water quality).
e) Rinse the product under cold water for at least 2 minutes, paying particular attention to the holes and places difficult to be cleaned.
f) Prepare fresh washing solution. Clean the surfaces and gaps of the product, carefully. Use suitable brushes to clean the holes. Clean the product immersed in the solution.
g) Rinse the product thoroughly under warm running water for at least 2 minutes, paying special attention to the gaps, blind holes, hinges and joints. When cleaning, use brushes and perform multiple reciprocating movements on the surface of the product.
h) Visually inspect the entire surface of the product for debris and impurity. Repeat the steps described in subsections c-k until the product is visually clean.
i) Ultrasound cleaning: prepare an aqueous cleaning solution at a temperature of 40+/- 2°C and pH of 10.4-10.8 (follow the information contained in the instructions prepared by the manufacturer of the cleaning agent, in respect of temperature, concentration, exposure time and water quality). Immerse fully the product in the aqueous cleaning solution and have it washed in ultrasounds for 15 minutes.
j) Rinse the product thoroughly under demineralized water, paying particular attention to the holes and places difficult to be cleaned.
k) Visually inspect the entire surface of the product for debris and impurity. Repeat the steps described in subsections c-k until the product is visually clean.
l) Use demineralized water for final rinsing of the device.
m) Dry the device thoroughly using disposable, soft, lint-free cloth or compressed air.
n) Prepare an aqueous solution of disinfecting agent at a temperature of 20+/- 2°C using 20g of the agent per 1 liter of water. Immerse the product in the solution, exposure time - 15min (follow the information contained in the instructions prepared by the manufacturer of the agent, in respect of temperature, concentration, exposure time and water quality).
o) After the exposure time, rinse the product thoroughly under demineralized water, paying particular attention to the holes and places difficult to be cleaned.
p) The cancelled instruments should be treated using a compressed air or air supplied from the syringe.
q) Dry the device thoroughly. It is recommended to dry the product in a dryer at a temperature ranging from 90°C to 110°C.
r) Visually inspect the entire surface of the device.
s) CAUTION: If the obstruction in the cannula cannot be removed as indicated in the Instructions for Use, the device should be considered at the end of its useful life and should be discarded in accordance with facility procedures and guidelines.
6) The automated method using a washer - disinfecter.
a) Equipment and materials: a washer - disinfecter, aqueous solutions of cleaning agent.
b) Cleaning in the washer-disinfector must be preceded by a manual and ultrasound cleaning, following the procedure described in subsections c-h of paragraph 5.
c) CAUTION: The equipment used for washing/disinfection should meet the requirements of ISO 15883, Procedure for cleaning in the washer-disinfector shall be performed according to internal hospital procedures, recommendations of the washer-disinfector manufacturer, and instructions for use prepared by the washing-disinfecting agent manufacturer.
d) The device should undergo the process of machine washing in the washer-disinfector using the following cycle parameters: (1) - pre-washing in cold tap water, duration - 2min; (2) - washing in an aqueous solution of cleaning agent at 55+/- 2°C and pH of 10.4 - 10.8, duration - 10min; (3) - rinsing under demineralized water, duration - 2min; (4) - thermal disinfection in demineralized water at 90°C, minimal duration - 5min; (5) - drying at the temperature ranging from 90°C to 110°C, duration - 40min.

5. Inspection

- 1) Each time before re-use and re-sterilization, all medical devices should be inspected.
- 2) All parts of the product should be checked for visible dirt and corrosion. Particular attention should be paid to:
a) Holes, grooves and gaps the debris could have been pressed into during use.
b) Places where dirt can be found, such as joints, latches, etc.
c) Generally unamplified visual inspection under good light conditions is sufficient.
- 3) Each time before re-use and re-sterilization, the functional check of the product should be performed, consisting of:
a) Verifying the connections in the mating instruments, such as tips, shafts and quick coupling devices.
b) Verifying the correct functioning of mechanisms, e.g. screw, ratchet, snap mechanism, etc.
c) Verifying all rotating devices for straightness (this can be simply achieved by rolling the device on a flat surface).
d) Verifying cutting edges for sharpness.
e) Verifying instruments for damage to material structure (cracks, dents, peeks, etc.).
f) Damaged or defective product cannot be approved for further use.
g) Prior to storage, the instrument must be checked for dryness.

7) CAUTION

- a) The ChM sp. z o.o. does not define the maximum number of uses appropriate for re-usable medical instruments. The useful life of these devices depends on many factors including the method and duration of each use, and the handling between uses. Careful and proper use reduces the risk of damage to the product and extends its serviceable life.
b) The manufacturer does not recommend using any preservatives on medical devices.

6) Packaging

1) Washed and dried devices shall be stored (if possible) in suitable stands; placed in special sterilization containers. Separate items should be packed in a packaging intended for the recommended steam sterilization. Sterilization containers, item packaging and packaging process itself have to meet the requirements of ISO 11607 standards. The packaging procedure must be performed in controlled purity conditions. The device must be packed so that during its removal from the packaging, when used, there is no risk for its re-contamination.

7) Sterilization

- 1) Washed, disinfected, and dried device shall undergo the sterilization process. The recommended method of sterilization is vacuum-type steam sterilization (with water vapor under overpressure):
a) temperature: 134°C
b) minimum exposure time: 7 min,
c) minimum drying time: 20 min.
2) CAUTION:
a) The sterilization process must be validated and routinely monitored in accordance with the requirements of EN ISO 17665-1.
b) Sterilization must be effective and in accordance with requirements of the EN 556-1 standard to ensure the required level of guaranteed sterility SAL 10⁻⁶ (where SAL stands for Sterility Assurance Level).
c) Device must not be sterilized in the packaging in which it was delivered, except specially designed sterilization containers.
d) The method of sterilization using ethylene oxide, gas plasma and dry heat should not be used, unless the Instructions for Use for the product contains specific sterilization recommendations using these methods.
e) The sterilization temperature for plastic products (PPSU, PEEK, PTFE, silicone) cannot be higher than 140°C.

6) STORAGE

1. 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 a clean and dry room, at room temperature and off the direct sunlight. If possible, instruments should be stored in suitable palettes; placed into specially designed sterilization containers.

7) 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. Instrument calibration is performed by the manufacturer. Any attempt of unauthorized modifications to the construction or factory setting of the torque devices can lead to a potential injury or damage to the product and is prohibited.

8) COMPATIBILITY

1. ChM specialist instrument sets are designed for insertion of ChM implants. A specific, illustrated operating technique that describes the proper use of instruments included in the instrument set that is designed for particular implant system, is provided together with such instrument set. It is not allowed to combine ChM instruments with products from other manufacturers. The physician bears responsibility for the use of the ChM instruments together with implants and instruments from other manufacturers.

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-001/06.18; Date of verification: June 2018

SYMBOL TRANSLATION - OBJASNIENIA SYMBOLI - ПОРЧЕЧЕННЯ ОБЖАСНЕННЬ - EXPLICACION DE LOS SIMBOLOS - SYMBOLERKLÄRUNG - SYMBOLI PŘEKLADY - TRADUZIONE SIMBOLI	
	Do not re-use - Nie używaj ponownie - Не використовуйте повторно - No reutilizar - Nicht wiederverwenden - Neupovzuje opakovaně - Non riutilizzare
	Do not sterilize - Nie sterylizuj ponownie - Не стерилізуйте повторно - No reesterilizar - Nicht resterilisieren - Neupovzuje sterilizacije - Non ristabilizzare
	Do not use if package is damaged - Nie używaj jeśli opakowanie jest uszkodzone - Не використовуйте якщо упаковка пошкоджена - No utilizar si el empaque está dañado - Nicht verwenden falls Verpackung beschädigt ist - Neupovzuje, pokud je obal poškozen - Non utilizzare se la confezione è danneggiata
	Consult Instructions for Use - Zaprzyj do instrukcji użytkownika - Обговоріть в якості посилання на призначення - Consultar instrucciones de uso - Siehe die Gebrauchsanweisung - Bitte sie näherem je possible - Consultare le istruzioni per l'uso
	Non-sterile - Nesterilnyy - Не стерильна - No estéril - Usterilni - Nesterilni - Non sterile
	Caution - Ostrożnie - Осторожно - Advertencia - Vorsicht - Varoitus - Avvertenza
	Sterilized using irradiation - Sterylizowany przez naświetlanie - Радиаційна стерилізація - Esterilizado mediante radiación - Sterilisiert durch Bestrahlung - Sterilizzato mediante irradiazione
	Sterilized using hydrogen peroxide - Sterylizowany nadtlenkiem wodoru - Стерилізація перекисом водню - Esterilizado con peróxido de hidrógeno - Sterilisiert mit Wasserstoffperoxid - Sterilizzazione a perossido di idrogeno
	Catalogue number - Numer katalogowy - Номер каталогу - Número de catálogo - Katalognummer - Katalogové číslo - Numeri di catalogo
	Batch code - Код партії - Код партия - Código de lote - Chargennummer - Číslo šarže - Codice del lotto
	Material - Матеріал - Материал - Material - Material - Materiale
	Quantity - Кількість - Количество - Cantidad - Menge - Množství - Quantität
	Use by - Увійди до - Мокловожити до - Usar antes de - Verwenden bis - Použít do - Da utilizzare entro il

Manufacturer: ChM sp. z o.o.
Lewickie 3b, 16-061 Juchnowiec K., Poland
tel.: +48 85 86 86 100 fax: +48 85 86 86 101
e-mail: chm@chm.eu www.chm.eu

ChM sp. z o.o.

Lewickie 3b
16-061 Juchnowiec Kościelny
Poland

tel. +48 85 86 86 100

fax +48 85 86 86 101

chm@chm.eu

www.chm.eu



CE 0197