



CERVICAL LOCKING PLATE

- *IMPLANTS*
- *INSTRUMENT SET 40.4820.600*
- *SURGICAL TECHNIQUE*



SYMBOLS DESCRIPTIONS



Titanium or titanium alloy



Length



Torx drive



Diameter



Recommended length range for a particular nail



Self-tapping



Self-drilling



Available in sterile/ non- sterile condition



See surgery technique



Caution - pay attention to a special procedure.



Perform the activity under X-Ray control.



Information about the next stages of a procedure.



Proceed to the next stage.



Return to the specified stage and repeat the activity.



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



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

www.chm.eu

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

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1. INTRODUCTION

Cervical locking plate system has been created to carry out one-, two-, three- or four-level cervical spine stabilization with anterior surgical approach.

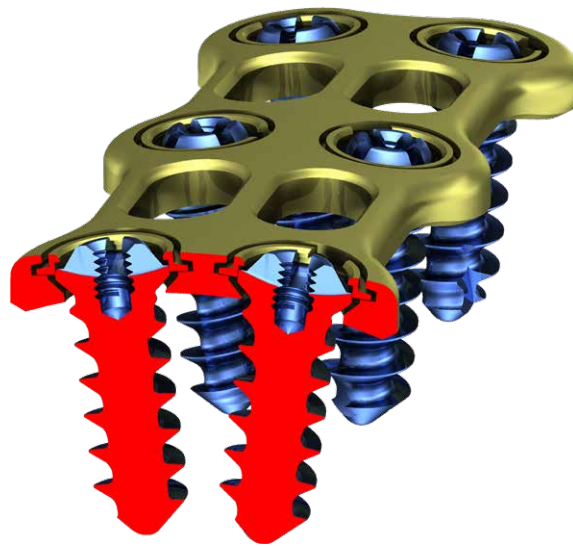
Indications:

- degenerative disc disease,
- fractures and instabilities,
- deformities,
- tumors.

The presented range of implants is made of materials 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.

System consists of:

- implants: cervical locking plates, screws,
- instrument set used in the surgery,
- Instructions for use.



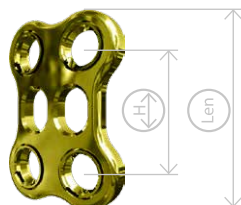
Features and benefits of cervical locking plate system:

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

2. IMPLANTS

CHARSPINE *system*

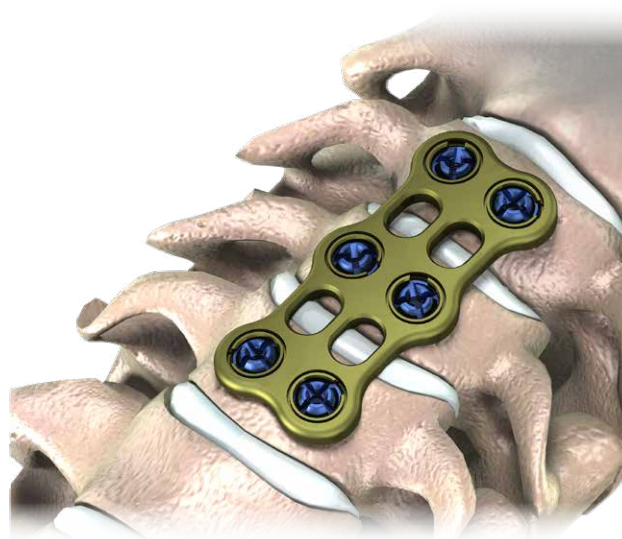
2.1. CERVICAL LOCKING PLATE



Len	H	Ti
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25	16	3.3133.025
28	18	3.3133.028

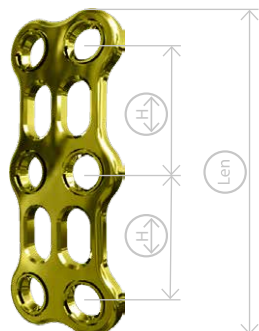


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3.3995.018	18				
3.3202.012	12				
3.3202.014	14				
3.3202.016	16	✓		✓	4.5
3.3202.018	18				
3.3997.012	12				
3.3997.014	14				
3.3997.016	16		✓	✓	4.5
3.3997.018	18				
3.3998.012	12				
3.3998.014	14				
3.3998.016	16	✓			4.0
3.3998.018	18				
3.3994.012	12				
3.3994.014	14				
3.3994.016	16		✓		4.0
3.3994.018	18				
3.3999.012	12				
3.3999.014	14				
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3.3999.018	18				
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3.3996.014	14				
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3.3996.018	18				



Stand for cervical plates - set

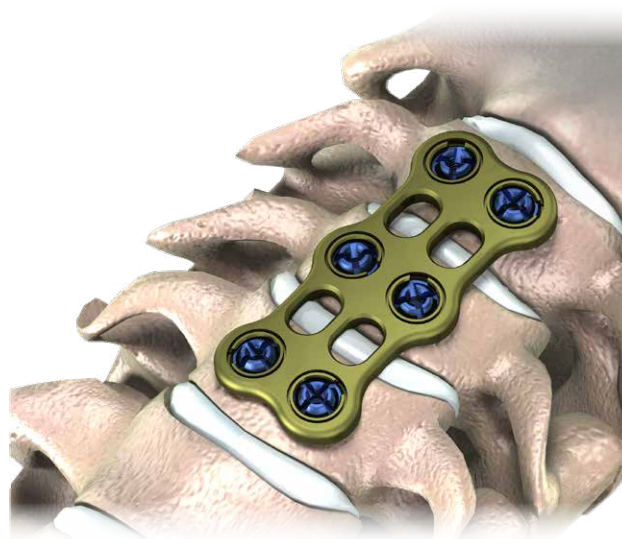
40.4865.000



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43	17	3.3133.043
46	18	3.3133.046



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Stand for cervical plates - set

40.4865.000



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53	15	3.3133.053
56	16	3.3133.056
59	17	3.3133.059
62	18	3.3133.062
65	19	3.3133.065



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3.3201.018	18				



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3.3202.018	18				



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3.3997.016	16		✓	✓	4.5
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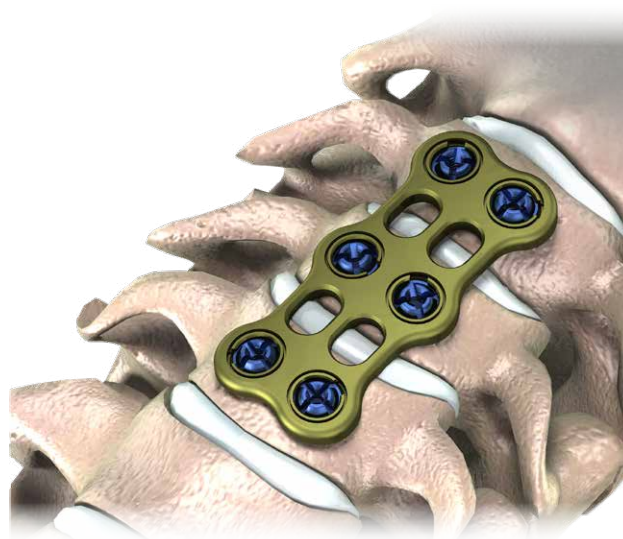
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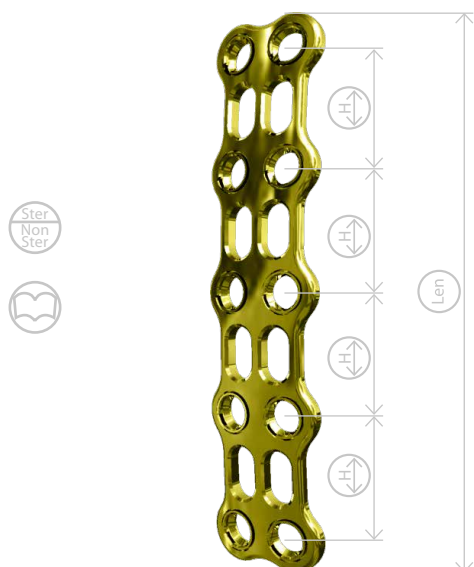


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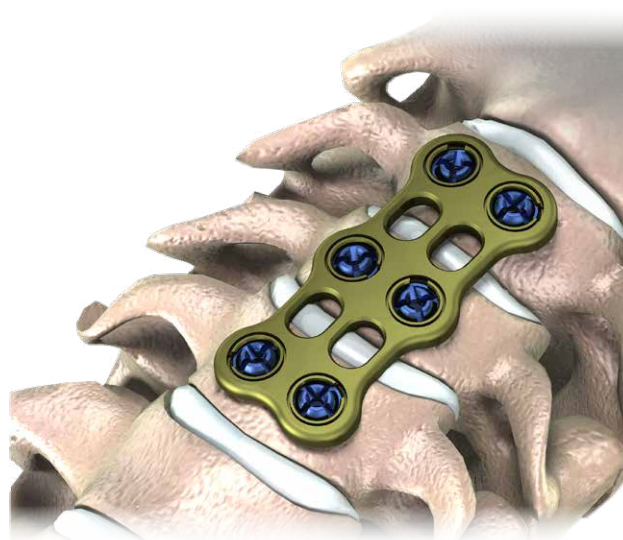
Stand for cervical plates - set

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77	17	3.3133.077
81	18	3.3133.081
85	19	3.3133.085
89	20	3.3133.089

	Ti	Len			VA	
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	3.3201.014	14				
	3.3201.016	16	✓		✓	4.0
	3.3201.018	18				
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	3.3995.014	14				
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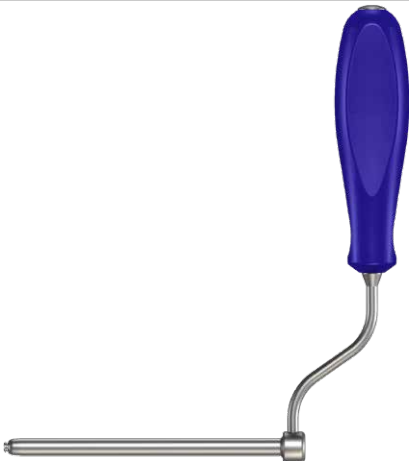








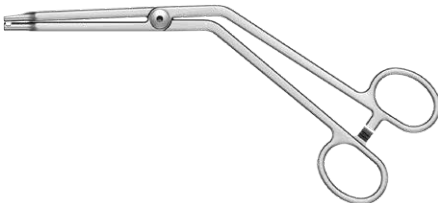





Stand for cervical plates - set

40.4865.000

3. INSTRUMENT SET

CHARSPINE *system*

40.4820.600	Name	Catalogue no.	Pcs
	Trocac C	40.4821.100	1
	Drill guide C - multiangular	40.4825.100	1
	Positioning screw C	40.4826.225	2
	Screwdriver for locking cervical screws	40.4828.100	1
	Plates bender	40.4830.000	1
	Drill with limiter C 2.2/12	40.4831.012	1
	Drill with limiter C 2.2/14	40.4831.014	1
	Drill with limiter C 2.2/16	40.4831.016	1
	Drill with limiter C 2.2/18	40.4831.018	1
	Screwdriver for cervical screws	40.5286.100	1
	Plate holder	40.4832.100	1
	Hole depth measure C	40.4833.100	1

40.4820.600	Name	Catalogue no.	Pcs
	Plate size measure	40.4834.100	1
	Drill guide C - rigid	40.4836.100	1
	Stand for instrument set for cervical locking plates	40.4838.600	1

4. SURGICAL APPROACH

Anterior approach to the cervical spine

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

Patient positioning

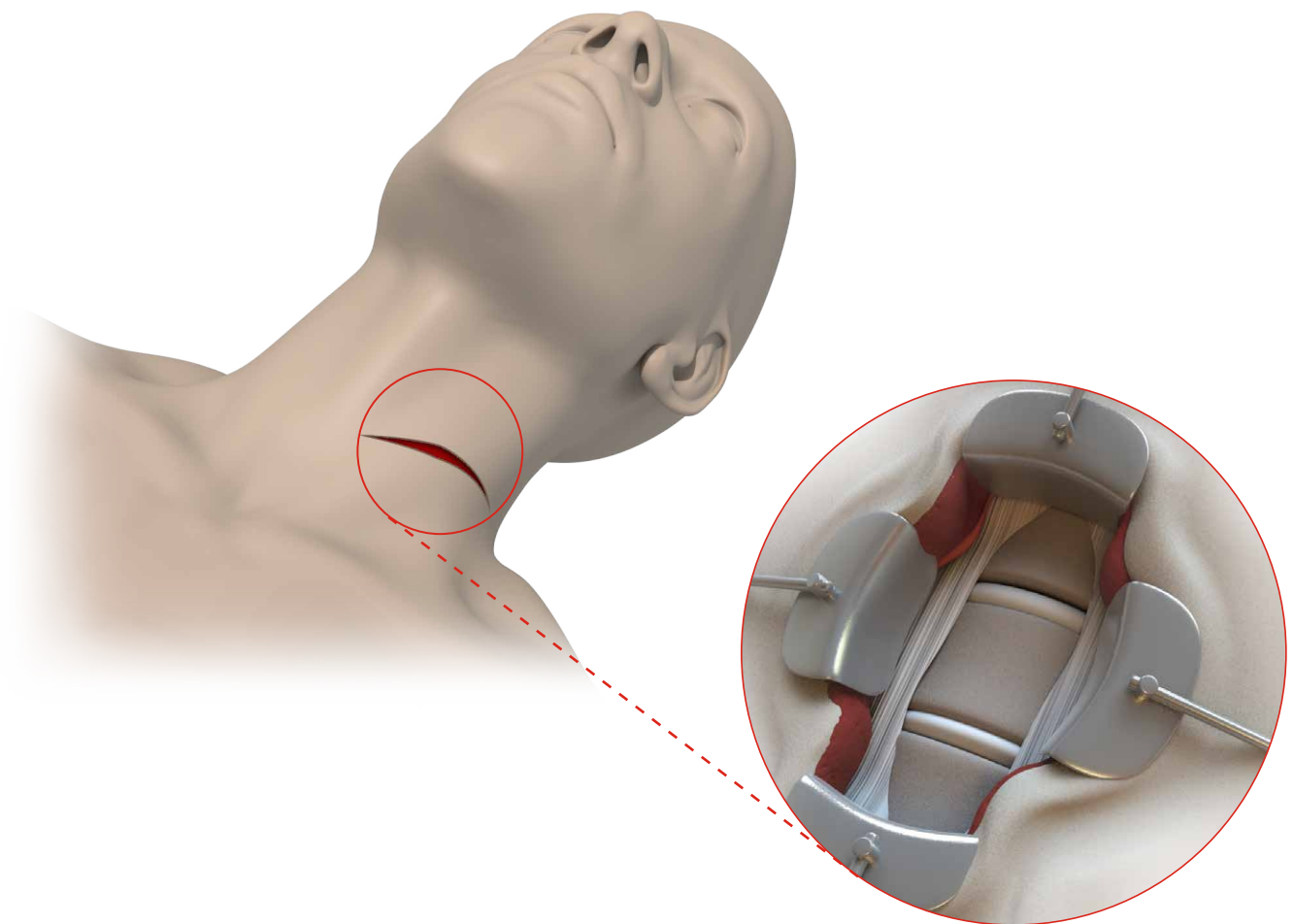
Patient is placed supine, with a small pillow between the shoulders to secure the neck in an extended position. Patient's head is turned in the opposite direction to the planned skin incision. If necessary, skeletal traction or loop may be used. This can be useful at a later stage of the operation, when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

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

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

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

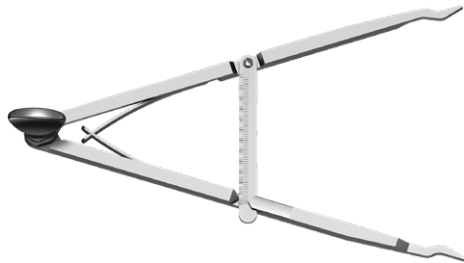
Removal of the osteophytes is essential for proper placement of a locking plate.



5. SURGICAL TECHNIQUE

5.1. PLATE SELECTION

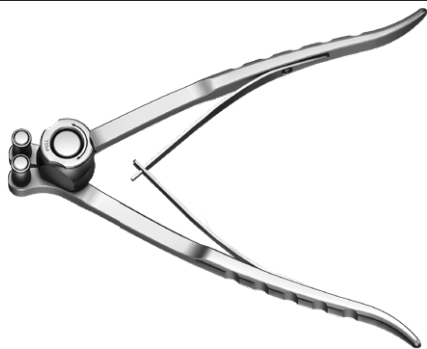
- 1 Before spinal decompression and plate implantation, use the plate size measure **[40.4834.100]** to define the proper size of the intervertebral graft or vertebral prosthesis. Implant the device and then use the same measure to choose adequate locking plate.



40.4834.100



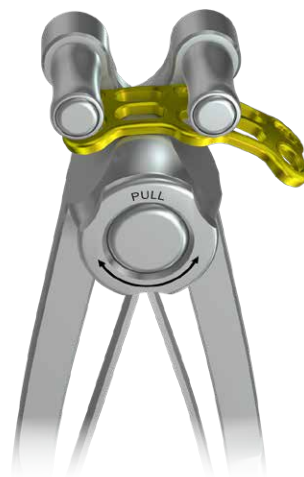
- 2 Make sure that factory-made curvature of the selected plate fits anatomical curvature of the spine. If needed, the plate curvature may be modified using the plates bender **[40.4830.000]**.



40.4830.000



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



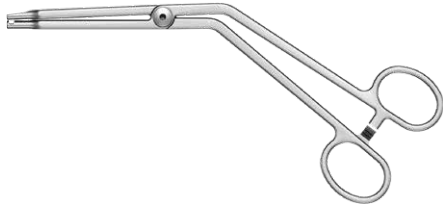
Lordotic curvature increase



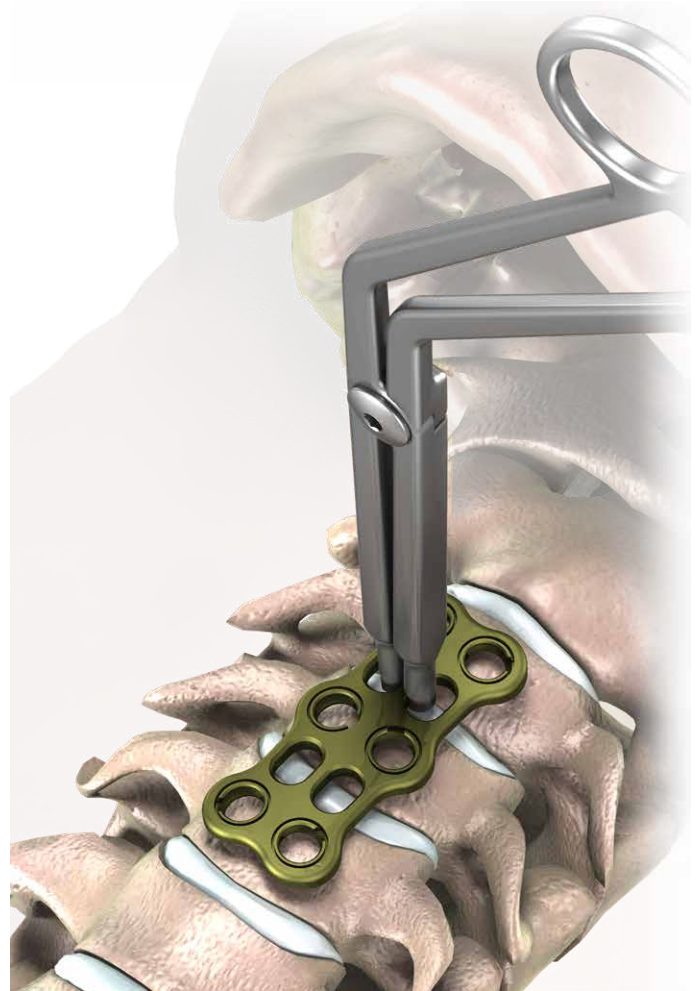
Lordotic curvature decrease

5.2. PLATE IMPLANTATION - TEMPORARY LOCKING USING POSITIONING SCREWS

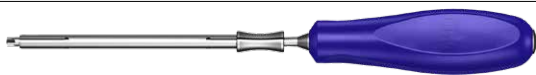
- 3 Use plate holder **[40.4832.100]** to position the plate on the surface of vertebral bodies.



40.4832.100



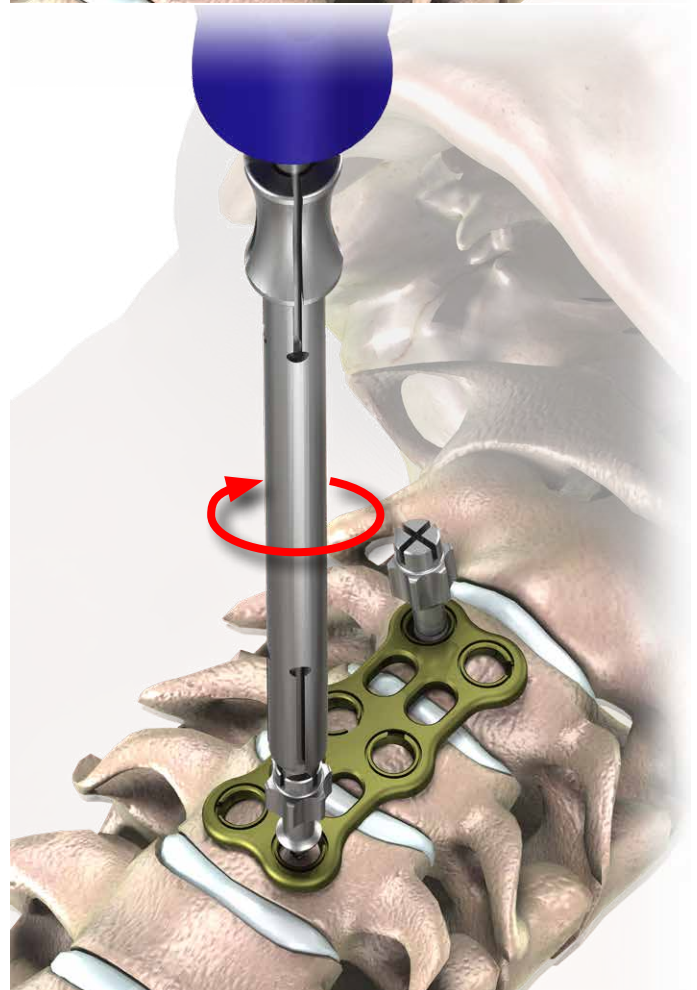
- 4 To maintain the desired position of the plate, attach it to the vertebral bodies using one or two positioning screws **[40.4826.225]**. Insert positioning screws using screwdriver for cervical screws - solid **[40.5286.100]** under the image intensifier control.



40.5286.100



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

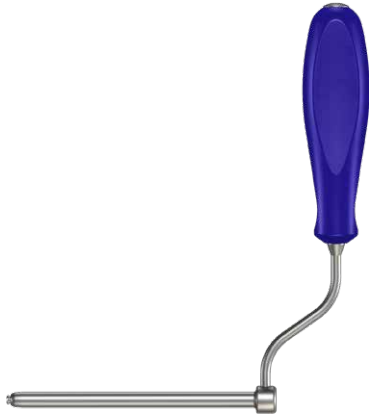


5.3. CORTICAL PENETRATIONS

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



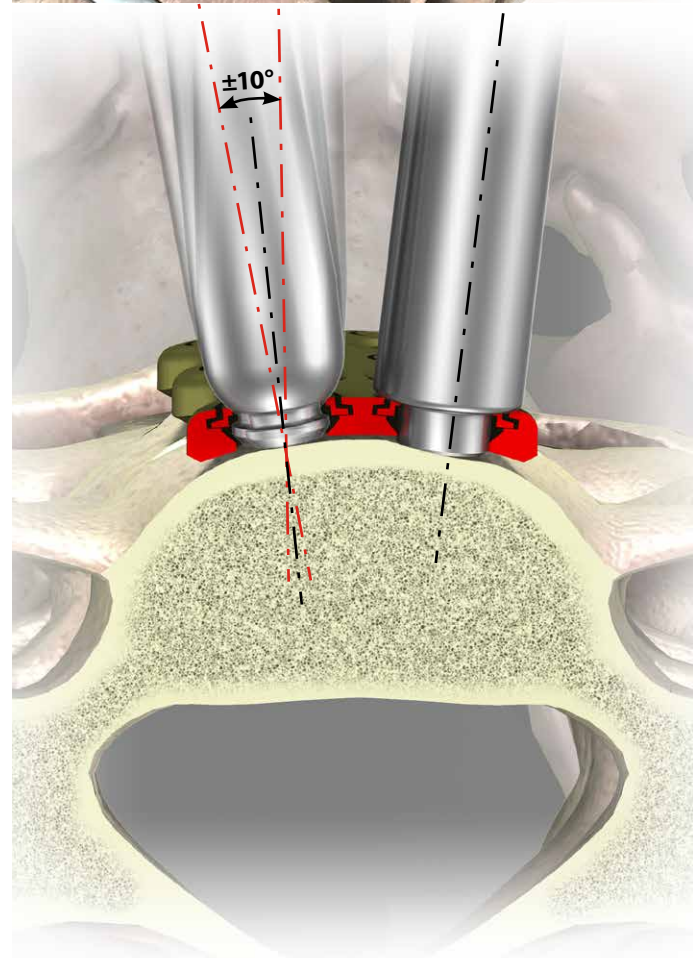
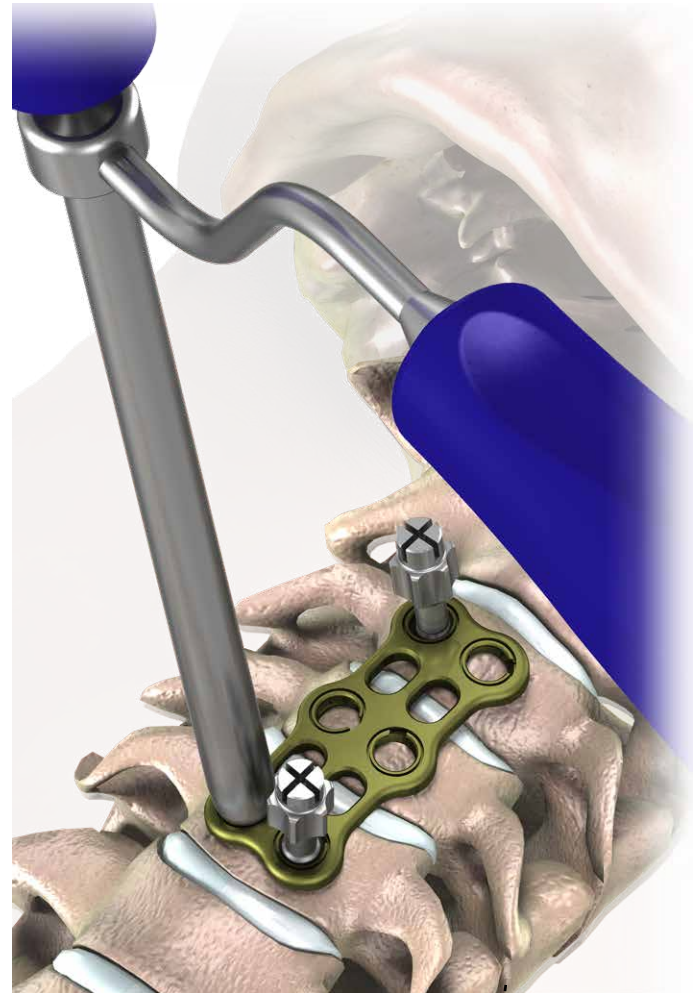
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40.4825.100



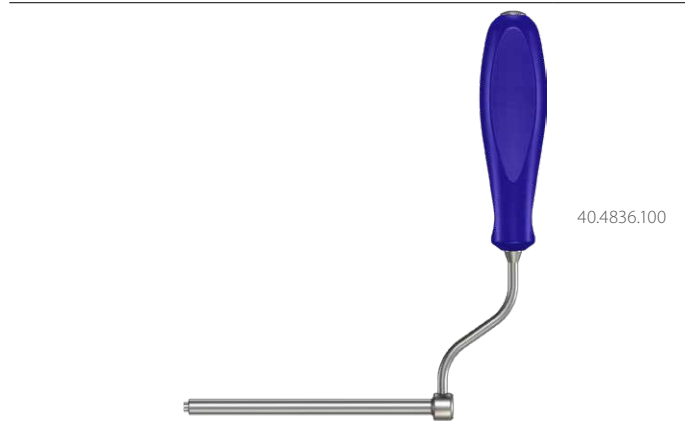
40.4836.100



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

5.4. HOLES DRILLING

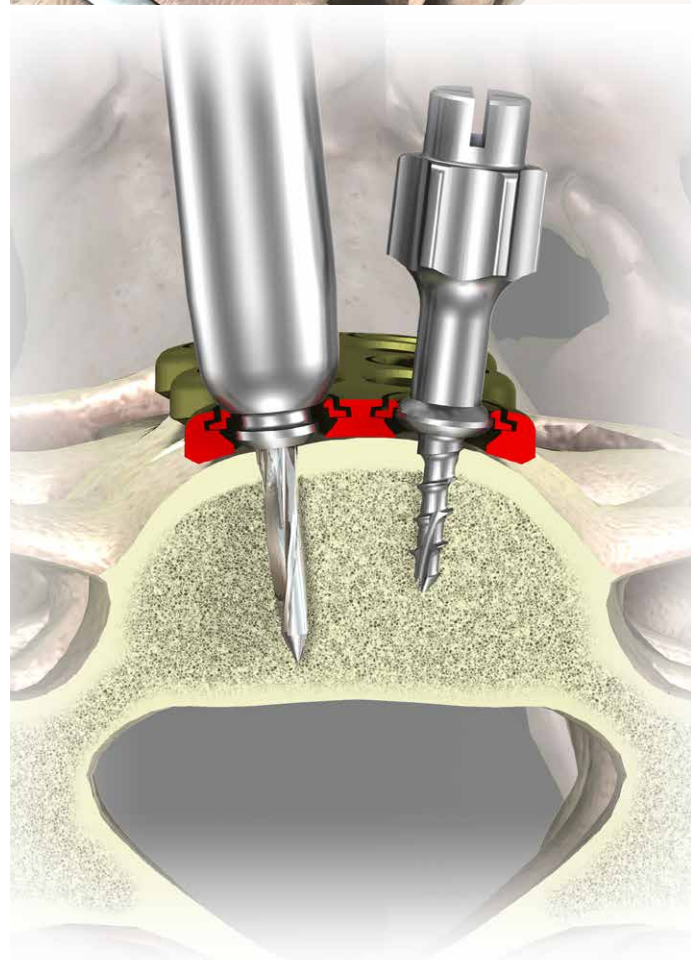
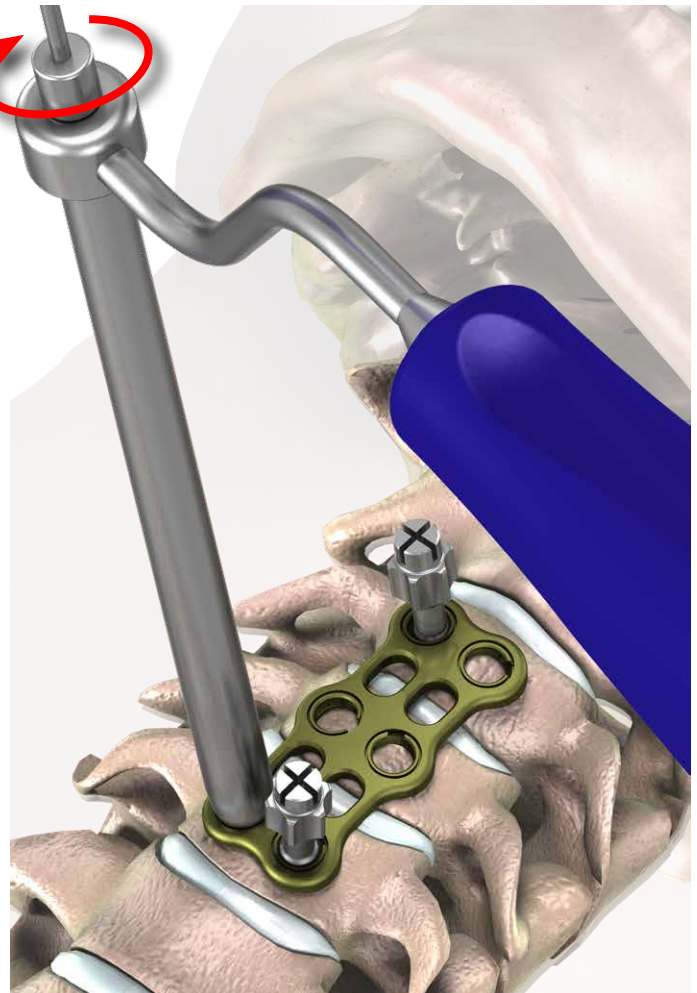
- 6 Should holes drilling be necessary, use a drill with limiter C **[40.4831.0xx]**. Based on X-Ray images, the appropriate drill length shall be chosen (*the drill sizes correspond to the lengths of locking screws*). Then insert the tip of drill guide C **[40.4825.100]** or **[40.4836.100]** into a hole for the locking screw and then the chosen drill. The drilling process shall be performed under X-Ray control until reaching the limiter of the drill.



The drilling process shall be controlled with image intensifier.



The trocar C **[40.4821.100]** and drills **[40.4831.0xx]** shall be used only with drill guides C **[40.4825.100]** or **[40.4836.100]**.

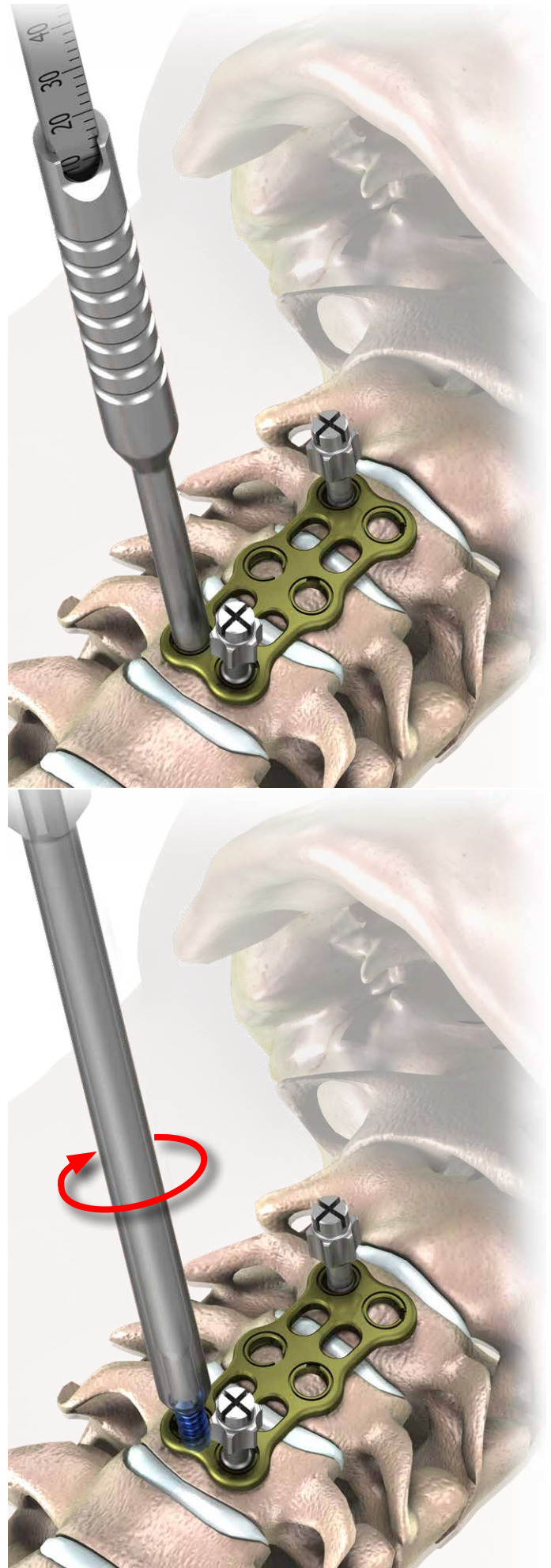


5.5. SCREWS SELECTION AND IMPLANTATION

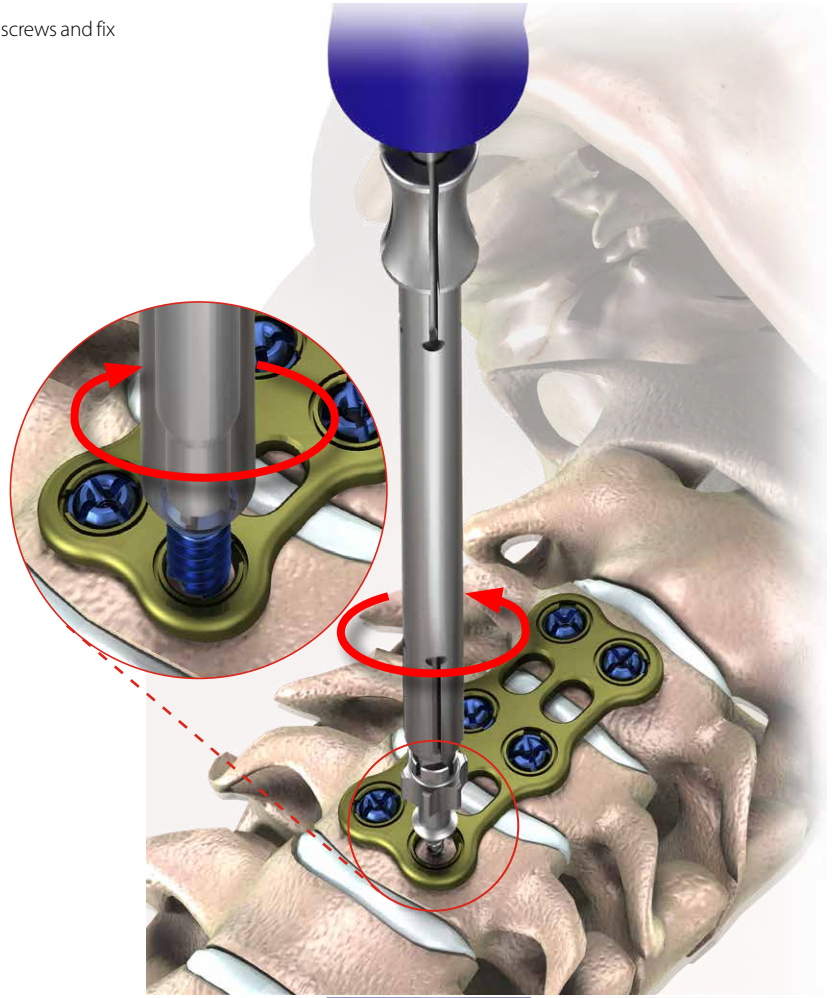
- 7 If needed, the drilled hole can be measured using the hole depth measure C **[40.4833.100]**. The tip of the measure shall be inserted into the hole until stop. Read the length of the locking screws on the measure scale. The value indicated on the device corresponds to the length of the locking screw.



- 8 The tip of the screwdriver for cervical screws - solid **[40.5286.100]** is inserted into the head of the locking screw that subsequently is secured on the tip by the screwdriver sleeve. The screw is inserted into the plate hole and tightened until 'click' sound is heard (*the safety mechanism integrated with the plate has been activated*).

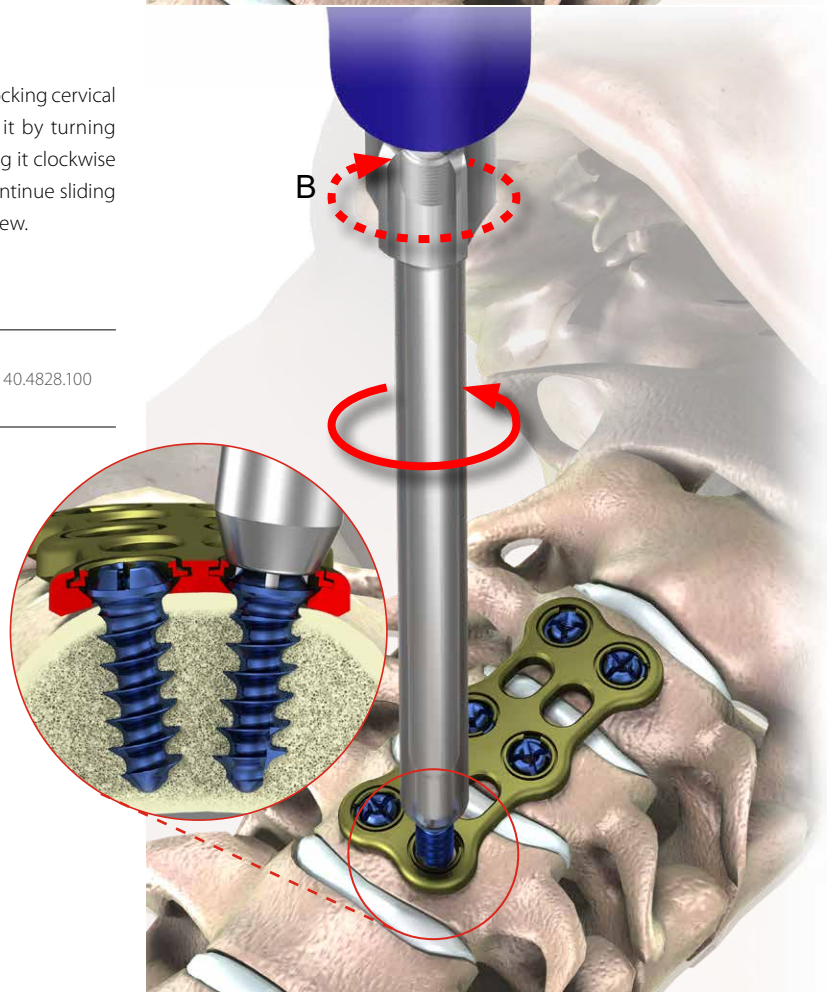


- 9 Having removed positioning screws, insert the other locking screws and fix the plate to the bone.



5.6. SCREWS REMOVAL

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



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