ST/45B

ChM®

ChM Pelvic System
CHARPEL system

RECONSTRUCTION PLATES
pelvis fixation

- *IMPLANTS*
- *INSTRUMENT SET 40.6000.500*
- *INSTRUMENT SET 40.6000.600*
- *INSTRUMENT SET 40.6000.700*
- *SURGICAL TECHNIQUE*

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SYMBOLS DESCRIPTIONS

	Caution - pay attention to the particular proceeding.
	Perform the activity with X-Ray control.
	Information about the next stages of the 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.

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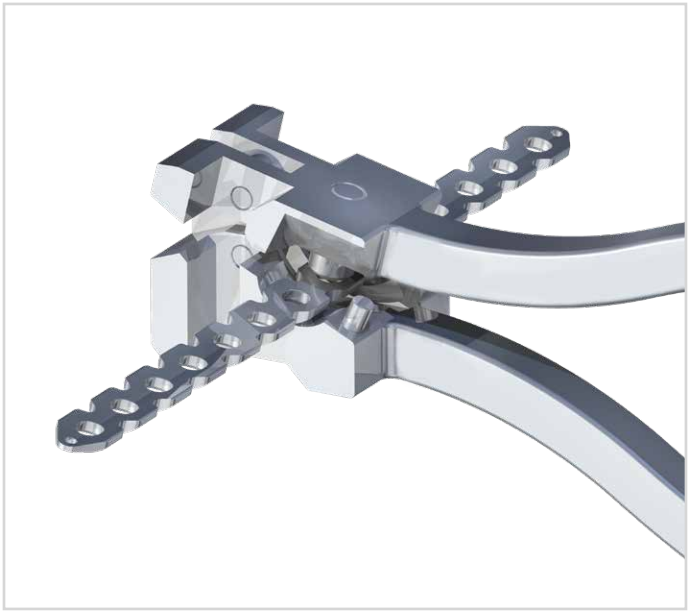
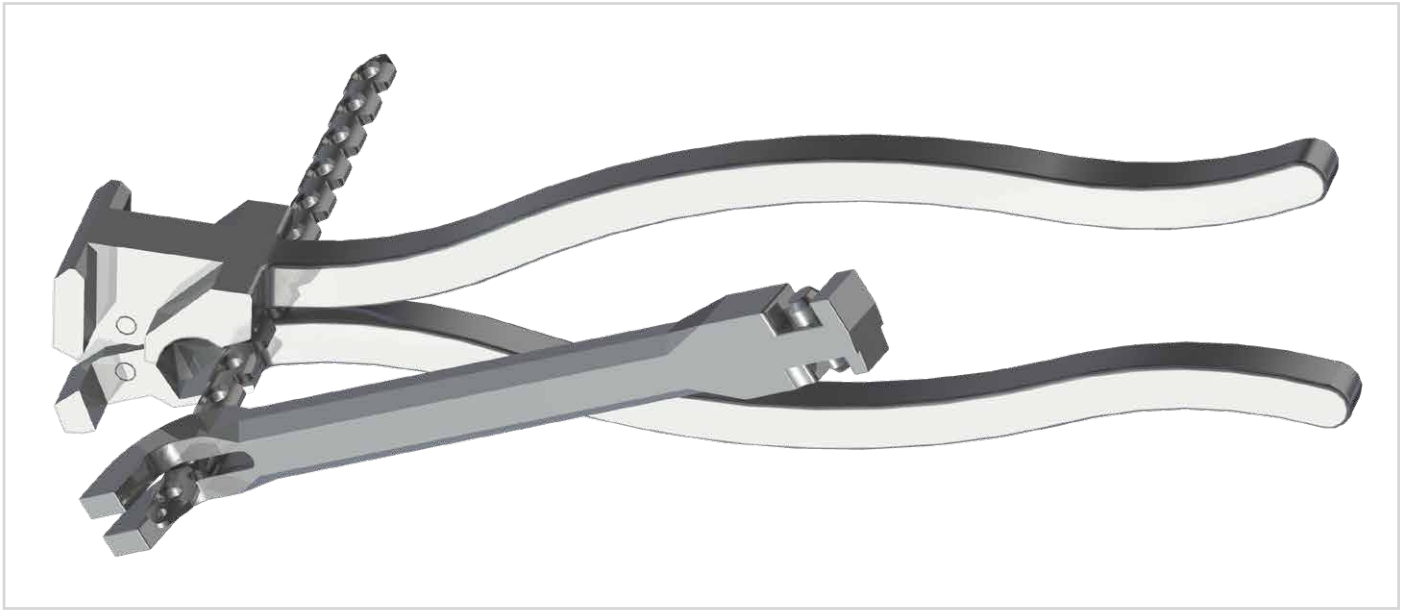
I. SELECTION AND CONTOURING OF PLATES

Wide size range of plates enables proper plate selection.
Locking plate contouring is not recommended due to possibility of damaging the threaded holes.
Bottom surface of the plate does not have to be in contact with a bone if locking screws are used. There is no necessity of accurate plates contouring. In most cases, initially contoured plates do not require any additional bending.
If the plate bending is necessary, remember not to deform threaded holes excessively. Plate holes may be slightly deformed; however, it can reduce their locking effectiveness and cause problems in subsequent insertion of a locking screw.

If it is necessary to bend the plate:

- perform bending between locking holes;
- do not bend the plate more than 20° – 25°;
- do not bend the plate back and forth;
- before bending, insert the locking screws in the bending area, as it decreases the threaded holes deformation degree.



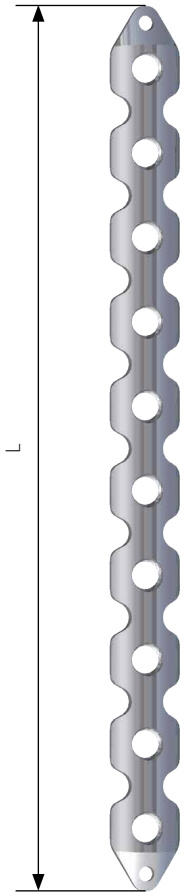


II. IMPLANTS

ChARPEL reconstruction plate 3.5mm straight

		Catalogue No.
O	**L** [mm]	**Steel**
5	66	1.7052.005
6	78	1.7052.006
7	90	1.7052.007
8	102	1.7052.008
9	114	1.7052.009
10	126	1.7052.010
12	150	1.7052.012
14	174	1.7052.014
16	198	1.7052.016
18	222	1.7052.018
20	246	1.7052.020
22	270	1.7052.022

O - threaded holes number in the plate



Steel
1.5200.016-095

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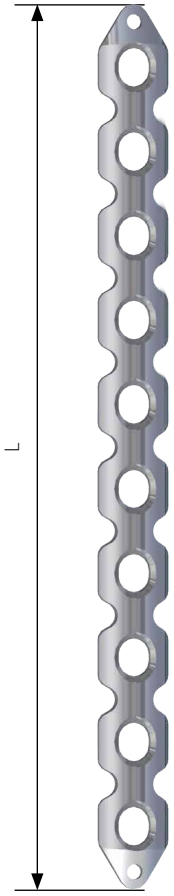
ChARPEL reconstruction plate 3.5 straight

		Catalogue No.
O	**L** [mm]	**Steel**
5	66	1.3118.005
6	78	1.3118.006
7	90	1.3118.007
8	102	1.3118.008
9	114	1.3118.009
10	126	1.3118.010
12	150	1.3118.012
14	174	1.3118.014
16	198	1.3118.016
18	222	1.3118.018
20	246	1.3118.020
22	270	1.3118.022

O - holes number in the plate

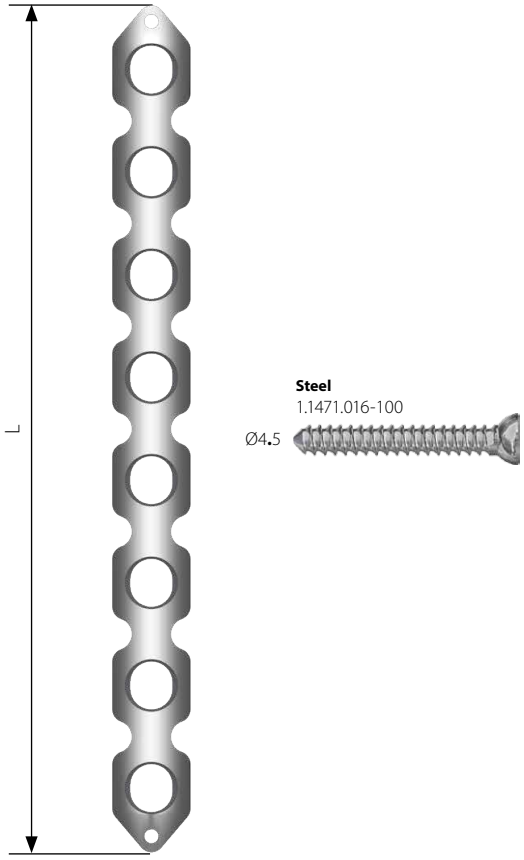


Steel
1.1306.014-110

ChARPEL reconstruction plate 4.5 straight

		Catalogue No.
O	**L** [mm]	**Steel**
3	52	1.3119.003
4	68	1.3119.004
5	84	1.3119.005
6	100	1.3119.006
7	116	1.3119.007
8	132	1.3119.008
9	148	1.3119.009
10	164	1.3119.010
11	180	1.3119.011
12	196	1.3119.012
13	212	1.3119.013
14	228	1.3119.014
15	244	1.3119.015
16	260	1.3119.016

O - holes number in the plate



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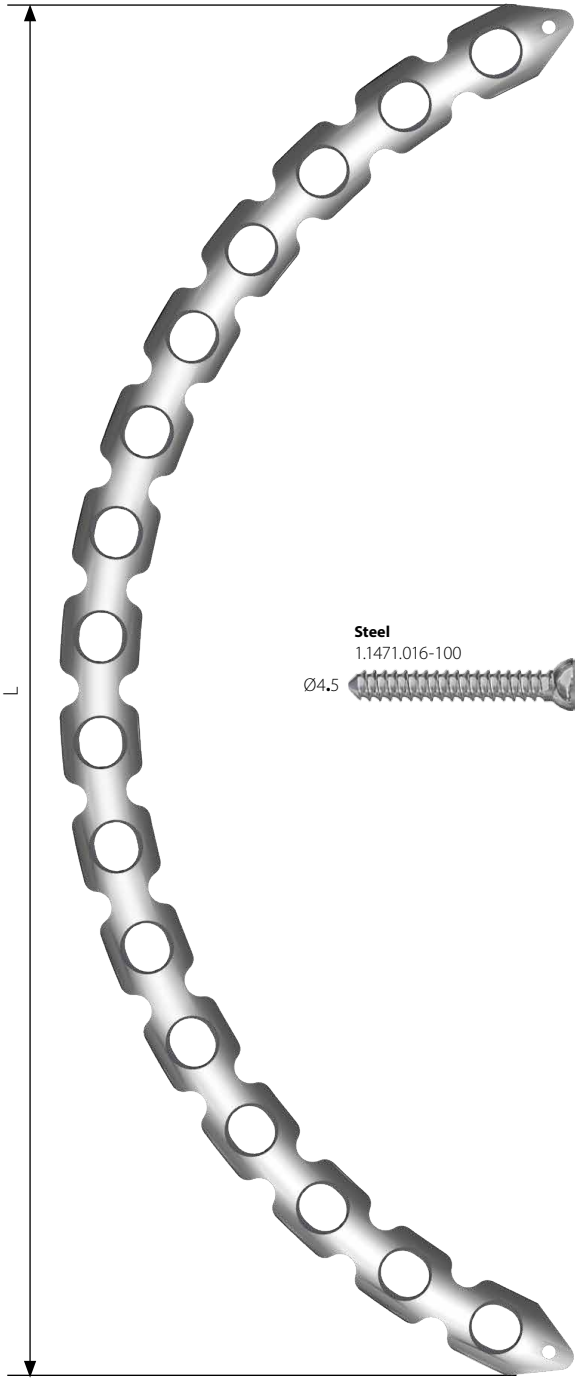
ChARPEL reconstruction plate R108 4.5mm

		Catalogue No.
O	**L** [mm]	**Steel**
4	72	1.3037.004
6	102	1.3037.006
8	129	1.3037.008
10	154	1.3037.010
12	175	1.3037.012
14	193	1.3037.014
16	208	1.3037.016

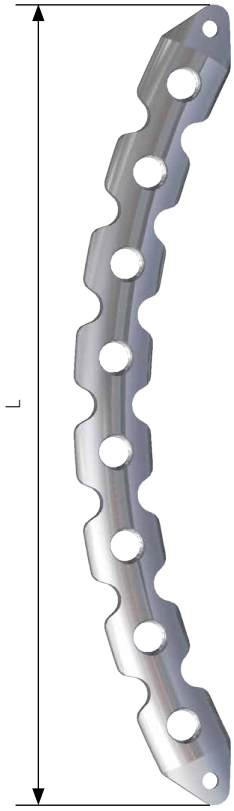
O - holes number in the plate



ChARPEL reconstruction plate 3.5mm R100

		Catalogue No.
O	**L** [mm]	**Steel**
4	59	1.7053.004
6	82	1.7053.006
8	104	1.7053.008
10	124	1.7053.010
12	143	1.7053.012
14	159	1.7053.014
16	173	1.7053.016
18	185	1.7053.018

O - threaded holes number in the plate



Steel
1.5200.016-095

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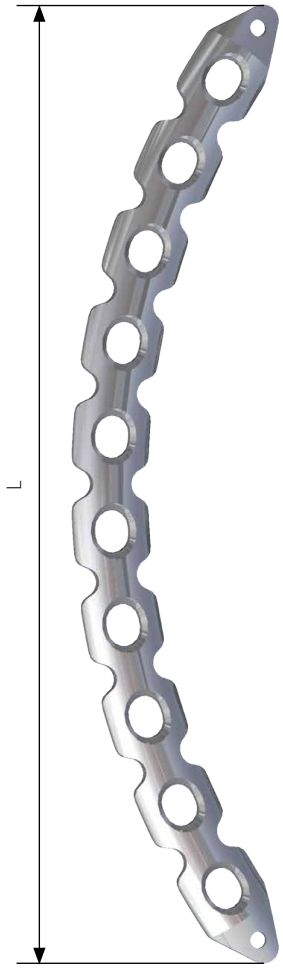
ChARPEL reconstruction plate R100 3.5mm

		Catalogue No.
O	**L** [mm]	**Steel**
4	59	1.3117.004
6	82	1.3117.006
8	104	1.3117.008
10	124	1.3117.010
12	143	1.3117.012
14	159	1.3117.014
16	173	1.3117.016
18	185	1.3117.018

O - holes number in the plate



Steel
1.1306.014-110

ChARPEL reconstruction J plate

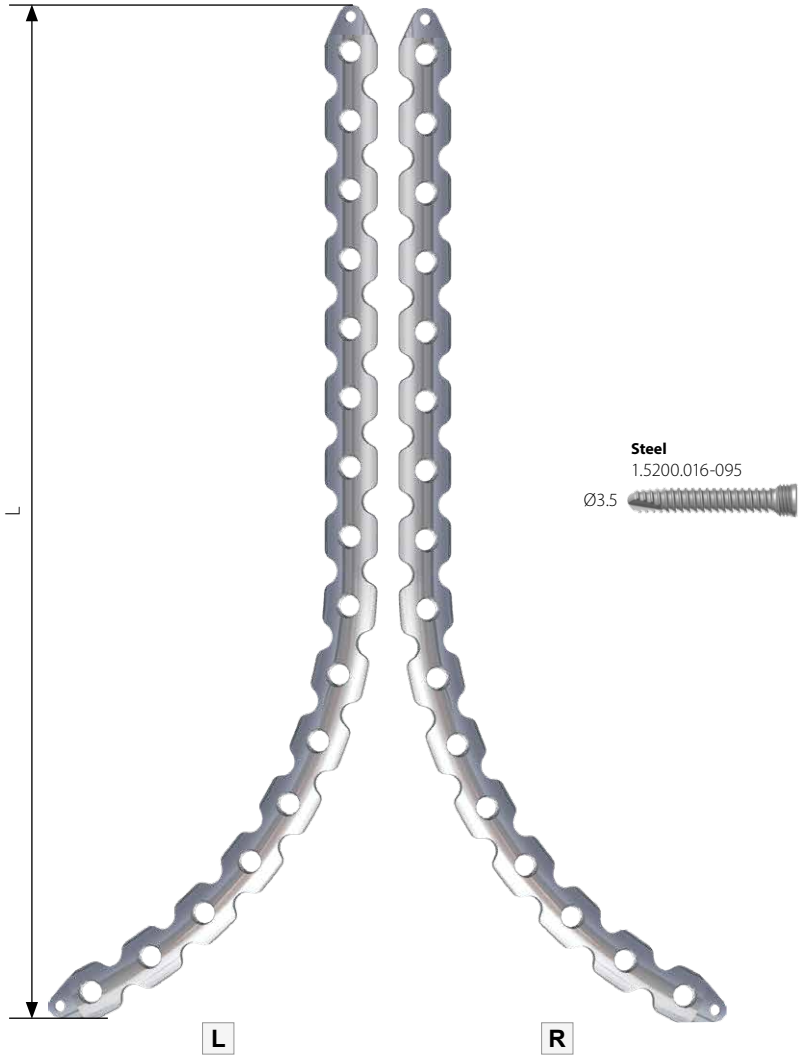
Left

		Catalogue No.
O	**L** [mm]	**Steel**
10	123	1.7013.010
12	143	1.7013.012
14	163	1.7013.014
16	181	1.7013.016

Right

		Catalogue No.
O	**L** [mm]	**Steel**
10	123	1.7012.010
12	143	1.7012.012
14	163	1.7012.014
16	181	1.7012.016

O - threaded holes number in the plate



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ChARPEL reconstruction J plate

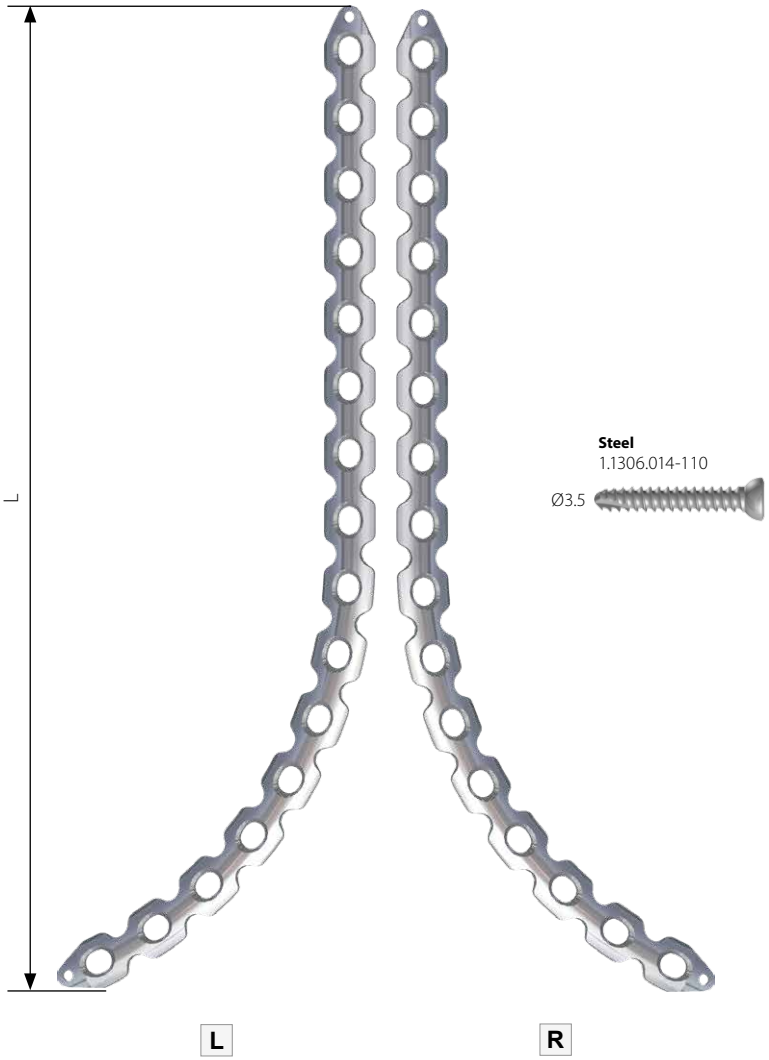
Left

		Catalogue No.
O	**L** [mm]	**Steel**
10	123	1.3036.010
12	143	1.3036.012
14	163	1.3036.014
16	181	1.3036.016

Right

		Catalogue No.
O	**L** [mm]	**Steel**
10	123	1.3035.010
12	143	1.3035.012
14	163	1.3035.014
16	181	1.3035.016

O - holes number in the plate

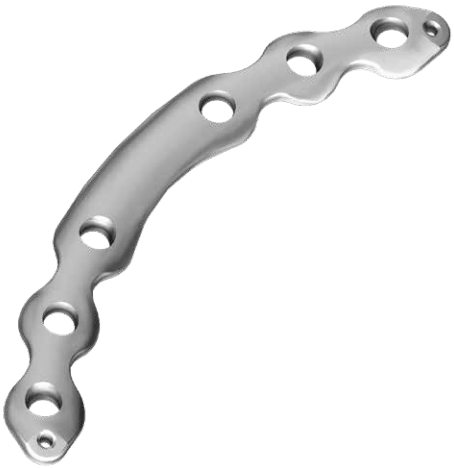


5.0ChLP symphysic plate

Left

		Catalogue No.
O	**L** [mm]	**Steel**
4	56.5	1.7046.104
6	83	1.7046.106

O - holes number in the plate



Steel
1.5200.012-095
Ø3.5

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Reconstruction plate

Left

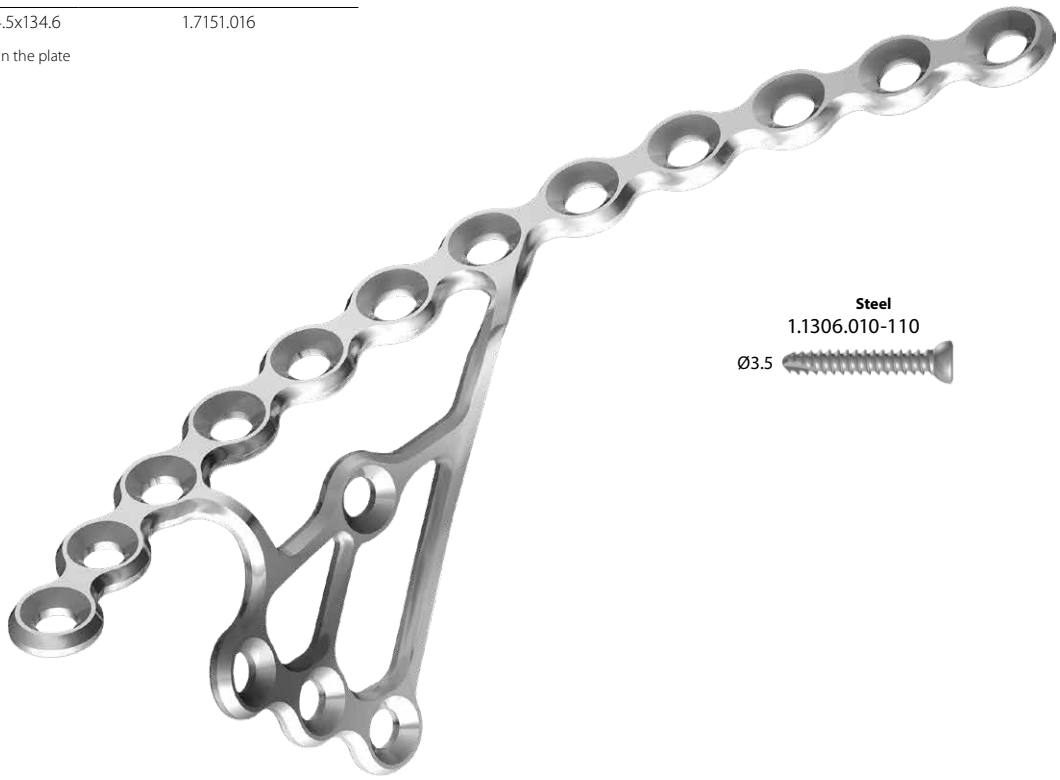
		Catalogue No.
O	**L** [mm]	**Steel**
16	44.5x134.6	1.7152.016

O - holes number in the plate

Right

		Catalogue No.
O	**L** [mm]	**Steel**
16	44.5x134.6	1.7151.016

O -holes number in the plate



Steel
1.1306.010-110
Ø3.5

L / **R**

5.0ChLP reconstruction plate

Left

		Catalogue No.
O	**L** [mm]	**Steel**
16	44.5x134.6	1.7252.016

O - holes number in the plate

Right

		Catalogue No.
O	**L** [mm]	**Steel**
16	44.5x134.6	1.7251.016

O - holes number in the plate

Steel
1.5200.012-095
Ø3.5

L / **R**

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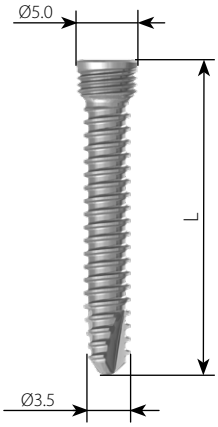
Reconstruction elastic plate 3.5

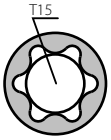
		Catalogue No.
O	**L** [mm]	**Steel**
1	18.5	1.3120.001
2	31.5	1.3120.002
3	44.5	1.3120.003

O - holes number in the plate

Steel
1.1306.010-110
Ø3.5

5.0ChLP self-tapping screw 3.5

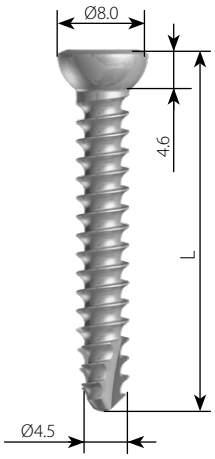


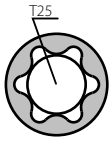


self-tapping

	Catalogue No.
L [mm]	**Steel**
12	1.5200.012
14	1.5200.014
16	1.5200.016
18	1.5200.018
20	1.5200.020
22	1.5200.022
24	1.5200.024
26	1.5200.026
28	1.5200.028
30	1.5200.030
32	1.5200.032
34	1.5200.034
36	1.5200.036
38	1.5200.038
40	1.5200.040
45	1.5200.045
50	1.5200.050
55	1.5200.055
60	1.5200.060
65	1.5200.065
70	1.5200.070
75	1.5200.075
80	1.5200.080
85	1.5200.085
90	1.5200.090
95	1.5200.095

Cortical self-tapping screw 4.5

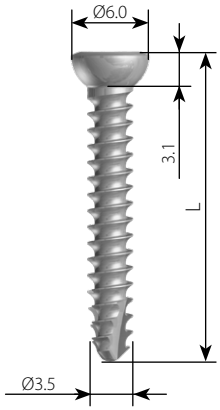


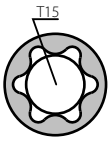


self-tapping

	Catalogue No.
L [mm]	**Steel**
16	1.1471.016
18	1.1471.018
20	1.1471.020
22	1.1471.022
24	1.1471.024
26	1.1471.026
28	1.1471.028
30	1.1471.030
32	1.1471.032
34	1.1471.034
36	1.1471.036
38	1.1471.038
40	1.1471.040
45	1.1471.044
50	1.1471.050
55	1.1471.055
60	1.1471.060
65	1.1471.065
70	1.1471.070
75	1.1471.075
80	1.1471.080
85	1.1471.085
90	1.1471.090
95	1.1471.095
100	1.1471.100

Cortical self-tapping screw 3.5





self-tapping

	Catalogue No.
L [mm]	**Steel**
10	1.1306.010
12	1.1306.012
14	1.1306.014
16	1.1306.016
18	1.1306.018
20	1.1306.020
22	1.1306.022
24	1.1306.024
26	1.1306.026
28	1.1306.028
30	1.1306.030
32	1.1306.032
34	1.1306.034
36	1.1306.036
38	1.1306.038
40	1.1306.040
45	1.1306.045
50	1.1306.050
55	1.1306.055
60	1.1306.060
65	1.1306.065
70	1.1306.070
75	1.1306.075
80	1.1306.080
85	1.1306.085
90	1.1306.090
95	1.1306.095
100	1.1306.100
105	1.1306.105
110	1.1306.110

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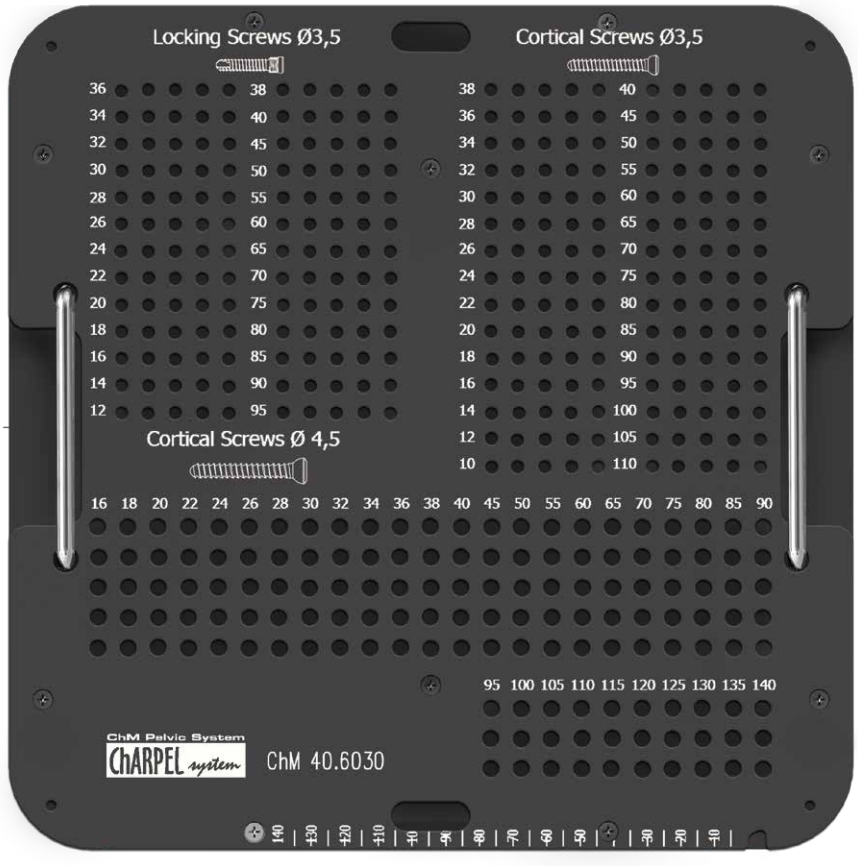
Stand for screws

No.	Name	Catalogue No.	Pcs.	
1	Stand for screws	40.6030.100	1	40.6030.000
2	Container solid bottom 1/2 306x272x184mm	12.0751.103	1	
3	Perforated aluminum lid 1/2 306x272x15mm Gray	12.0751.200	1	

implants not included

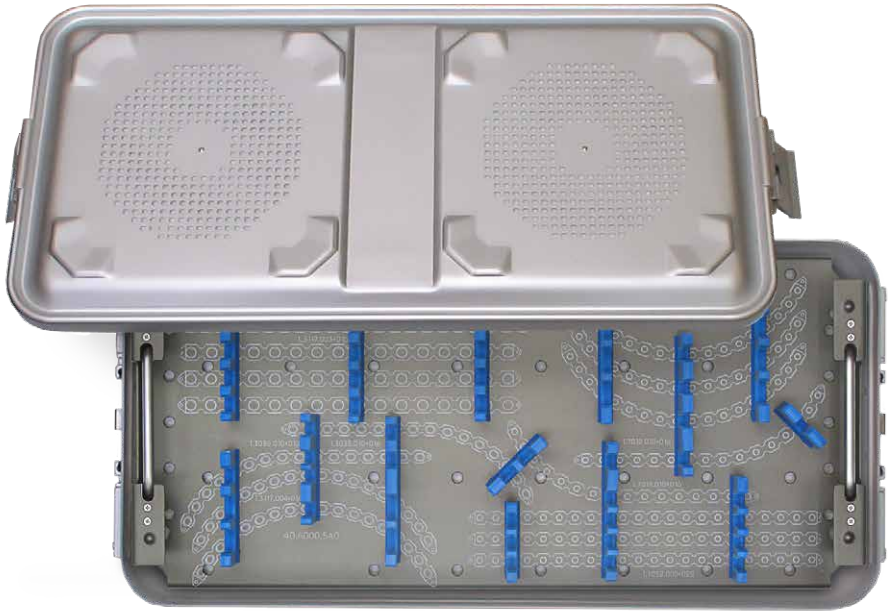


40.6030.100

40.6030.000

Palette for implants

No.	Name	Catalogue No.	Pcs.	
1	Stand for implants	40.6018.300	1	40.6000.540
2	Container solid bottom 1/1 595x275x86mm	12.0750.100	1	
3	Perforated aluminum lid 1/1 595x275x15mm Gray Покрышка алюминиевая перфорированная 1/1 595x275x15мм Серая	12.0750.200	1	



40.6000.540

Plate trials

No.	Catalogue no.	Name
1	40.6019.000	Plate 1.3035 trial
2	40.6020.000	Plate 1.3036 trial
3	40.6021.000	Plate 1.3117 trial
4	40.6022.000	Plate 1..3118 trial
5	40.6023.000	Plate 1..3119 trial

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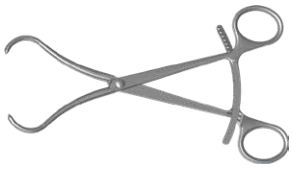
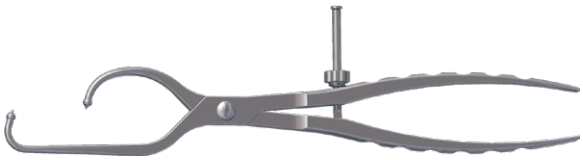
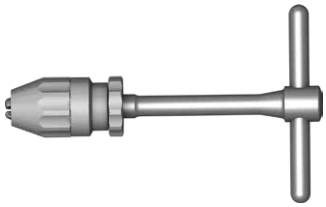
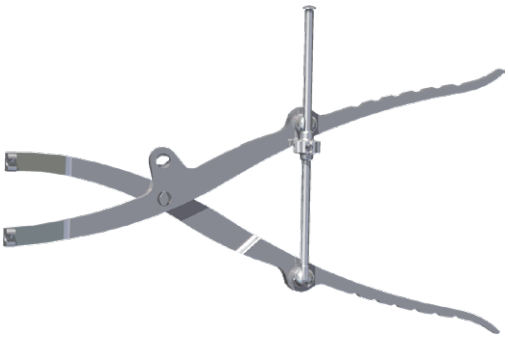
III. INSTRUMENTS

III.1. INSTRUMENT SET FOR PELVIC FIXATION 40.6000.500

No.		Name	Catalogue No.	Pcs.
1		Reduction long forceps 1x1	40.6007.000	1
2		Reduction long forceps 2x1	40.6008.000	1
3		Reduction ratchet pliers with sharp tips	40.6009.000	1
4		Compression forceps	40.6016.000	1
5		Reduction asymetric pliers	40.6017.000	1
6		STEINMANN handle	40.0987.200	1
7		Stand for instrument set for pelvic fixation	40.6018.100	1
8		Retractor for bone straight	40.6001.000	1
9		Temporary persuader	40.6002.000	2
10		Retractor for bone with handle	40.6003.000	1

No.		Name	Catalogue No.	Pcs.
11		Angular reduction curved forceps long	40.6004.000	1
12		Angular reduction curved forceps short	40.6005.000	1
13		Angular reduction straight forceps	40.6006.000	1
14		Latch swinging round	40.6028.000	2
15		Latch swinging rectangular	40.6029.000	2
16		Reduction regulating forceps	40.6015.000	1
17		Elevator 24	40.2199.001	1
18		LANGE-HOHMANN elevator modif. 30	40.2190.001	1
19		Stand for instrument set for pelvic fixation	40.6018.150	1
20		Drill 2.5/250	40.2049.251	2
21		Drill 3.2/250	40.2053.251	2
22		Drill 3.5/250	40.1363.251	2
23		Drill 4.5/250	40.1387.251	2
24		Kirschner wire 2.0/220	40.4815.220	4
25		Drill with scale 2.8/250	40.5653.251	2
26		Compression pin 6x200	40.6035.200	2
27		Setting-compressing screw 2.8/180	40.5674.128	2
28		Guide sleeve 5.0/2.8	40.5673.028	4
29		Torque limiting ratchet handle 2Nm	40.6652.000	1

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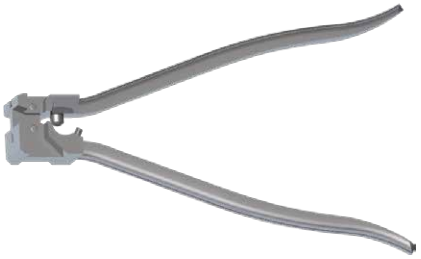
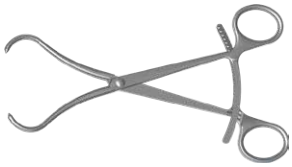
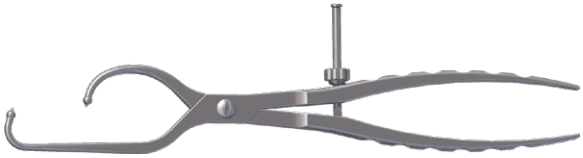
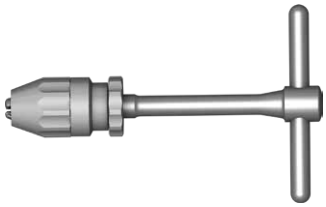
No.		Name	Catalogue No.	Pcs.
30		Screwdriver tip T15	40.5677.150	1
31		Screwdriver tip T 25-3/16	40.5684.150	1
32		Compression guide 2.5	40.4804.025	1
33		Holder for screws 4.5	40.6027.000	1
34		Holder for screws 3.5	40.6026.000	1
35		Cortical tap HA3.5	40.5926.000	1
36		Cortical tap HA34.5	40.5647.100	1
37		Bender for reconstruction plates straight	40.6013.000	2
38		Multiplane bender for reconstruction plates	40.6014.000	1
39		Hole depth measure L-150mm	40.2667.100	1
40		Stand for instrument set for pelvic fixation	40.6018.200	1
41		Container with solid bottom 1/1 595x275x135mm	12.0750.102	2
42		Perforated aluminum lid 1/1 595x275x15mm Gray	12.0750.200	2

III.2. INSTRUMENT SET FOR PELVIC FIXATION 40.6000.600

No.		Name	Catalogue No.	Pcs.
1		Reduction long forceps 1x1	40.6007.000	1
2		Reduction long forceps 2x1	40.6008.000	1
3		Reduction ratchet pliers with sharp tips	40.6009.000	1
4		Compression forceps	40.6016.000	1
5		Reduction asymetric pliers	40.6017.000	1
6		STEINMANN handle	40.0987.200	1
7		Stand for instrument set for pelvic fixation	40.6018.100	1
8		Retractor for bone straight	40.6001.000	1
9		Temporary persuader	40.6002.000	2
10		Retractor for bone with handle	40.6003.000	1
11		Angular reduction curved forceps long	40.6004.000	1

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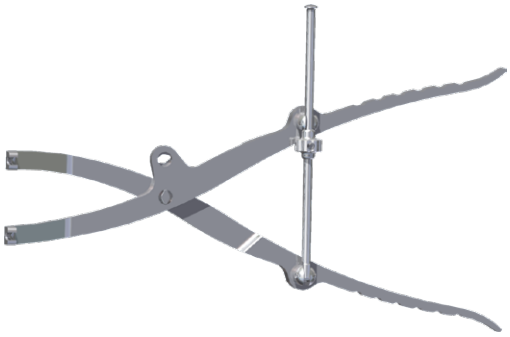
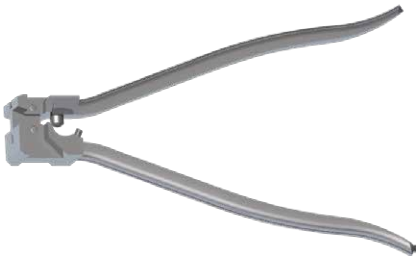
No.		Name	Catalogue No.	Pcs.
12		Angular reduction curved forceps short	40.6005.000	1
13		Angular reduction straight forceps	40.6006.000	1
14		Latch swinging round	40.6028.000	2
15		Latch swinging rectangular	40.6029.000	2
16		Reduction regulating forceps	40.6015.000	1
17		Elevator 24	40.2199.001	1
18		LANGE-HOHMANN elevator modif. 30	40.2190.001	1
19		Stand for instrument set for pelvic fixation	40.6018.150	1
20		Drill 2.5/250	40.2049.251	2
21		Drill 3.2/250	40.2053.251	2
22		Drill 3.5/250	40.1363.251	2
23		Drill 4.5/250	40.1387.251	2
24		Kirschner wire 2.0/220	40.4815.220	4
25		Compression pin 6x200	40.6035.200	2
26		Torque limiting ratchet handle 2Nm	40.6652.000	1
27		Screwdriver tip T15	40.5677.150	1
28		Screwdriver tip T 25-3/16	40.5684.150	1
29		Compression guide 2.5	40.4804.025	1
30		Holder for screws 4.5	40.6027.000	1
31		Holder for screws 3.5	40.6026.000	1

No.		Name	Catalogue No.	Pcs.
32		Cortical tap HA3.5	40.5926.000	1
33		Cortical tap HA34.5	40.5647.100	1
34		Hole depth measure L-150mm	40.2667.100	1
35		Bender for reconstruction plates straight	40.6013.000	2
36		Multiplane bender for reconstruction plates	40.6014.000	1
37		Stand for instrument set for pelvic fixation	40.6018.200	1
38		Container with solid bottom 1/1 595x275x135mm	12.0750.102	2
39		Perforated aluminum lid 1/1 595x275x15mm Gray	12.0750.200	2

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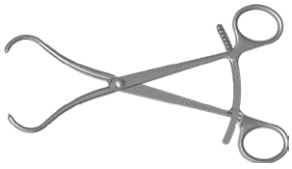
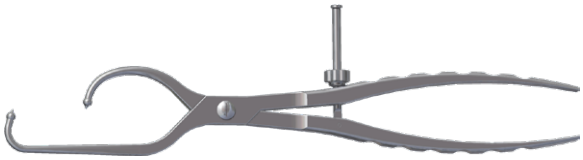
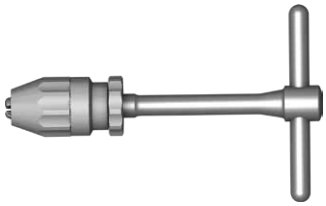
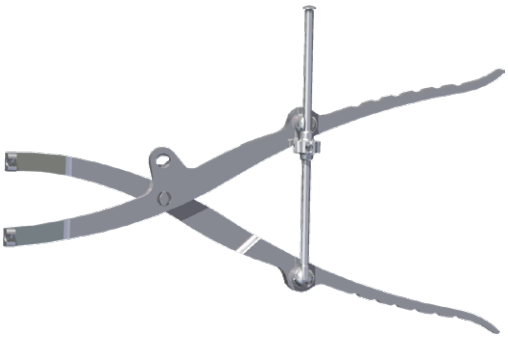
III.3. INSTRUMENT SET FOR PELVIC FIXATION – REPOSITIONING 40.6000.700

No.		Name	Catalogue No.	Pcs.
1		Reduction long forceps 1x1	40.6007.000	1
2		Reduction long forceps 2x1	40.6008.000	1
3		Reduction ratchet pliers with sharp tips	40.6009.000	1
4		Compression forceps	40.6016.000	1
5		Reduction asymetric pliers	40.6017.000	1
6		STEINMANN handle	40.0987.200	1
7		Stand for instrument set for pelvic fixation	40.6018.100	1
8		Retractor for bone straight	40.6001.000	1
9		Temporary persuader	40.6002.000	2
10		Retractor for bone with handle	40.6003.000	1

No.		Name	Catalogue No.	Pcs.
11		Angular reduction curved forceps long	40.6004.000	1
12		Angular reduction curved forceps short	40.6005.000	1
13		Angular reduction straight forceps	40.6006.000	1
14		Latch swinging round	40.6028.000	2
15		Latch swinging rectangular	40.6029.000	2
16		Reduction regulating forceps	40.6015.000	1
17		Elevator 24	40.2199.001	1
18		LANGE-HOHMANN elevator modif. 30	40.2190.001	1
19		Stand for instrument set for pelvic fixation	40.6018.150	1
20		Container with solid bottom 1/1 595x275x135mm	12.0750.102	1
21		Perforated aluminum lid 1/1 595x275x15mm gray	12.0750.200	1

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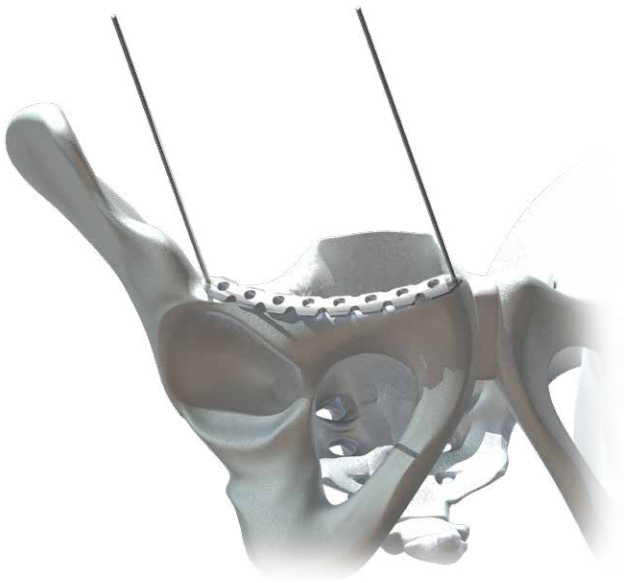
IV. SURGICAL TECHNIQUE

IV.1. TEMPORARY PLATE ATTACHMENT

When fracture is reduced and the plate position is confirmed, determine its temporary location using Kirschner wires 2.0 **[40.4815.220]**. Wires can be inserted in proximal holes of the plate and the most distal one.

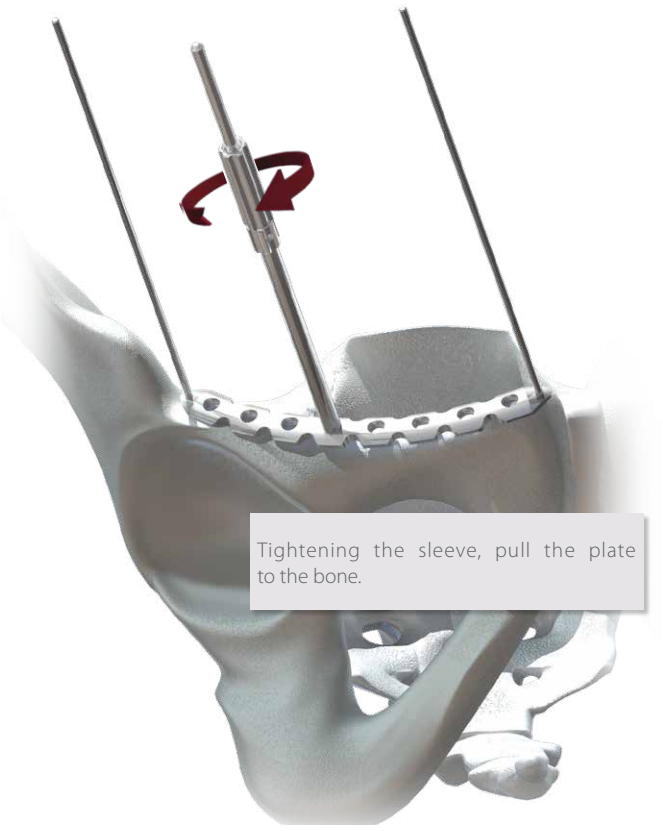
Confirm the plate position is correct by taking X-Ray image.



NOTE: The Setting-compressing screw 2.8/180 **[40.5674.128]** can be used to stabilize and tighten the plate up to the bone for temporary purposes. The screw is to be inserted via the guide sleeve 5.0/2.8 **[40.5673.028]**

Locking screw Ø3.5 can be inserted in the hole after removal of the setting-compressing screw 2.8/180.

Insert self-drilling pin of setting-compressing screw.

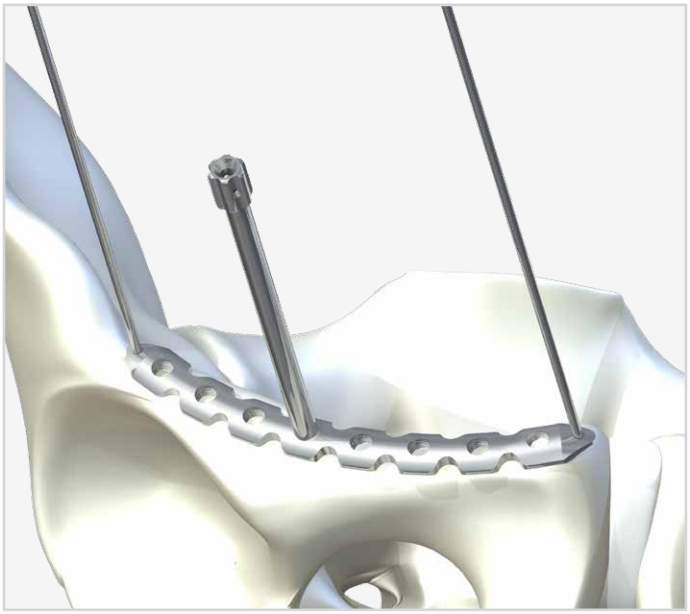


Tightening the sleeve, pull the plate to the bone.

IV.2. LOCKING SCREW INSERTION

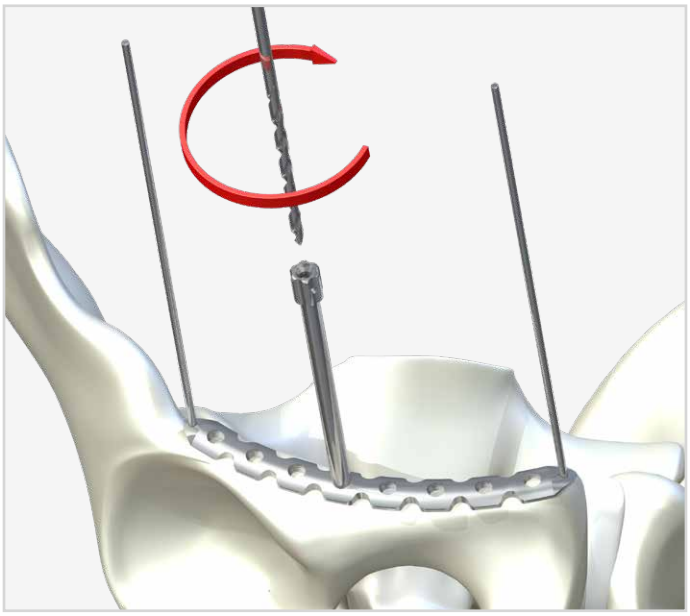
IV.2.1. Guide sleeve screwing

Insert the guide sleeve 5.0/2.8 **[40.5673.028]** into the plate.



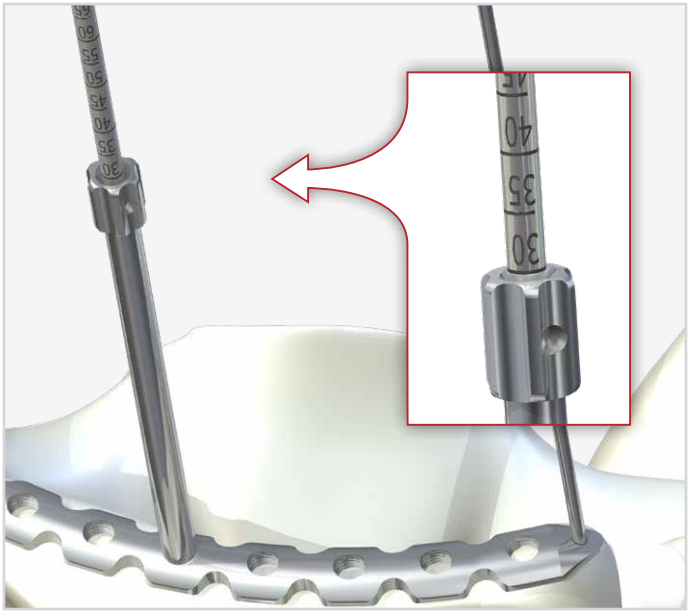
IV.2.2. Drilling the hole

Ream the hole using the drill with scale 2.8/250 **[40.5653.251]** until the desired depth is reached.

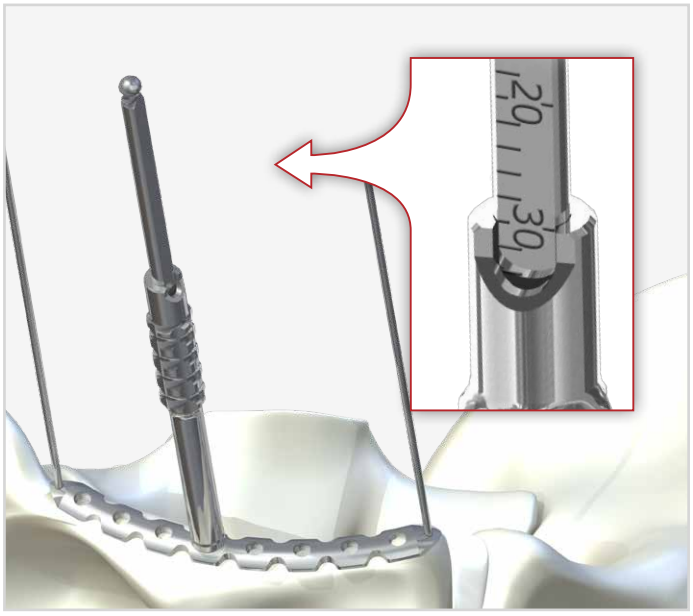


IV.2.3. Hole depth measurement

OPTION I: Read the value on the drill with scale **[40.5653.251]**.

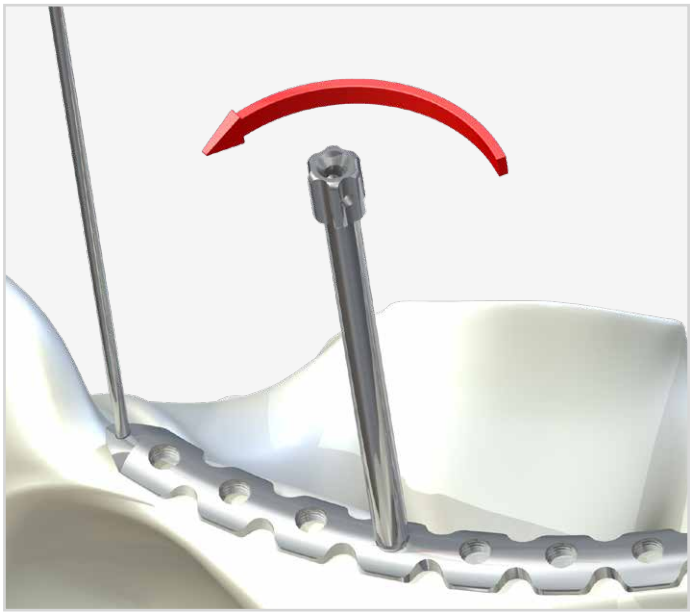


OPTION II: After removal of the guide sleeve 5.0/2.8 **[40.5673.028]**, the screw length may be defined with the use of the depth measure **[40.2667.100]**.

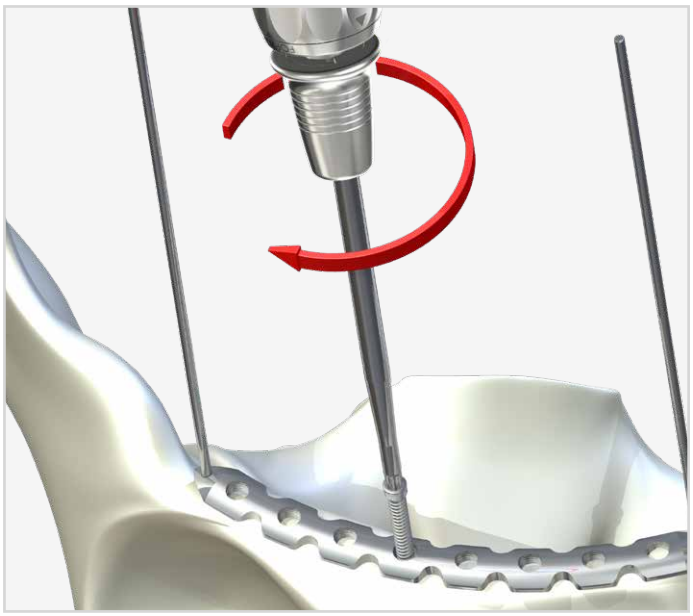


IV.2.4. Screw insertion

Remove the guide sleeve 5.0/2.8 **[40.5673.028]**.



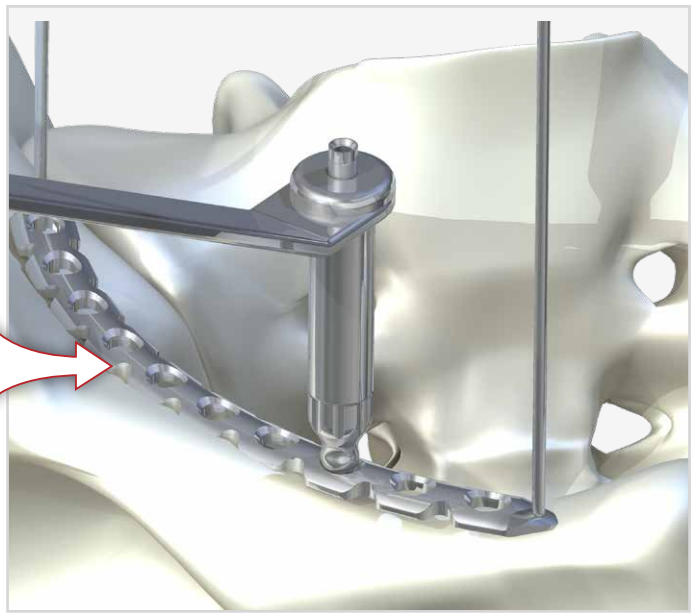
Insert the locking screw using the torque limiting ratchet handle 2Nm **[40.6652]** and proper screwdriver tip.



IV.3. CORTICAL SCREW INSERTION

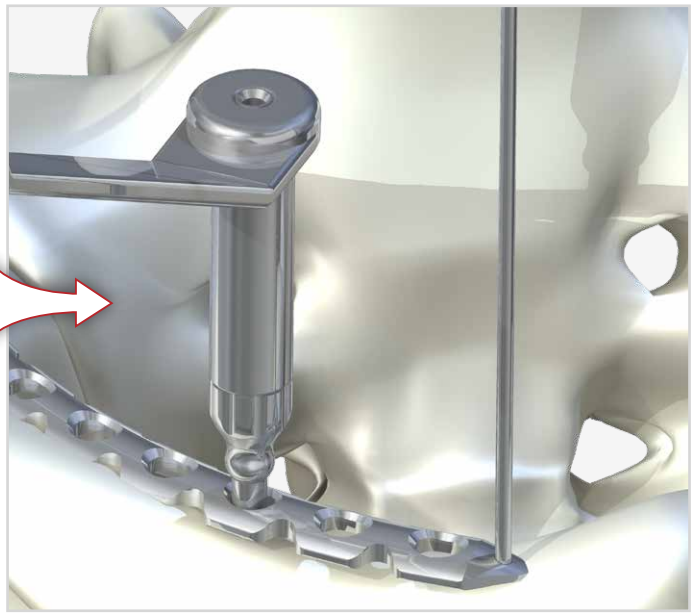
IV.3.1. Compression guide setting

Set the compression guide 2.5 **[40.4804.025]** in a desired position:



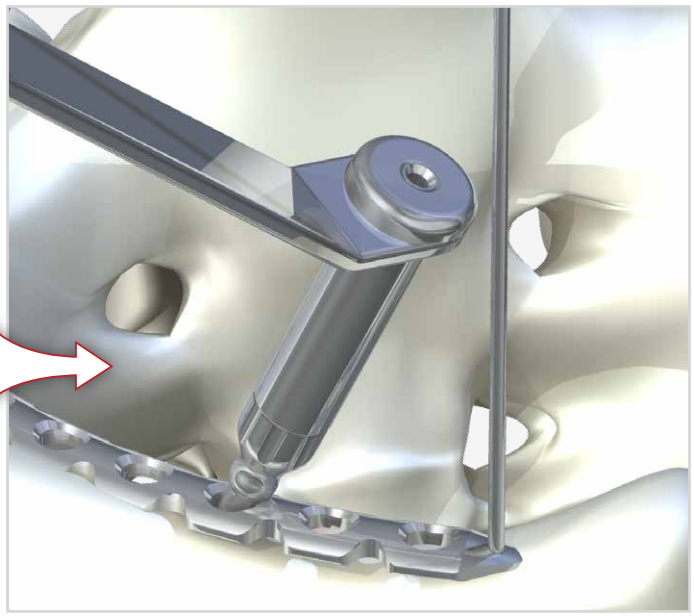
OPTION I: Neutral position

Press the guide to the plate to achieve the neutral position for screw insertion.



OPTION II: Compressive position

Move the guide without pressure to the edge of a compression hole to achieve the compression position for screw insertion.

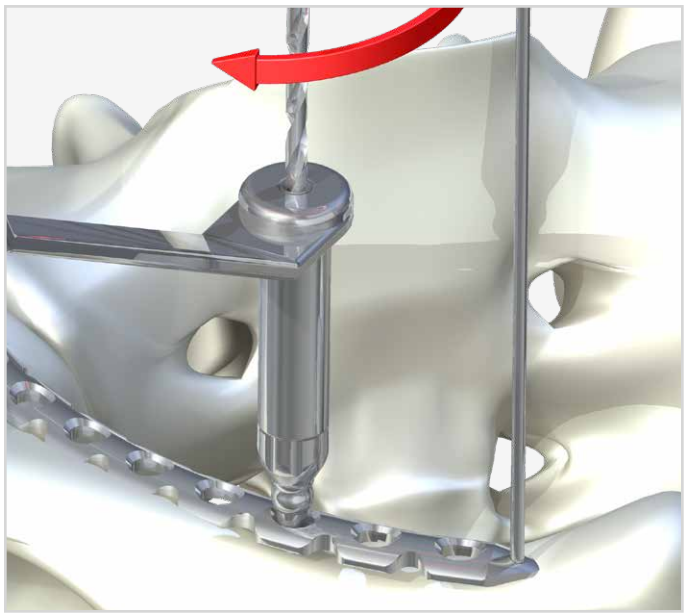


OPTION III: Angular position

Angular positioning of the guide is also available.

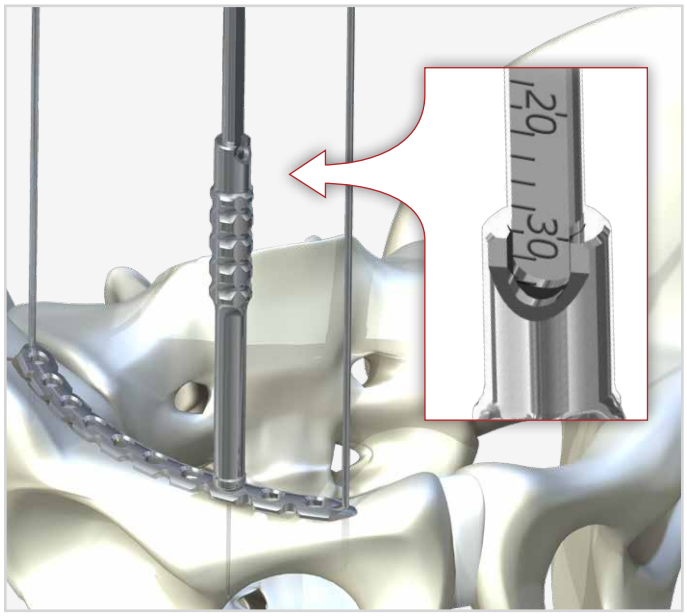
IV.3.2. Drilling

Drill the hole through both cortices in a desired position for the cortical screw Ø3.5 insertion using the drill Ø2.5/250 **[40.2049.251]**.



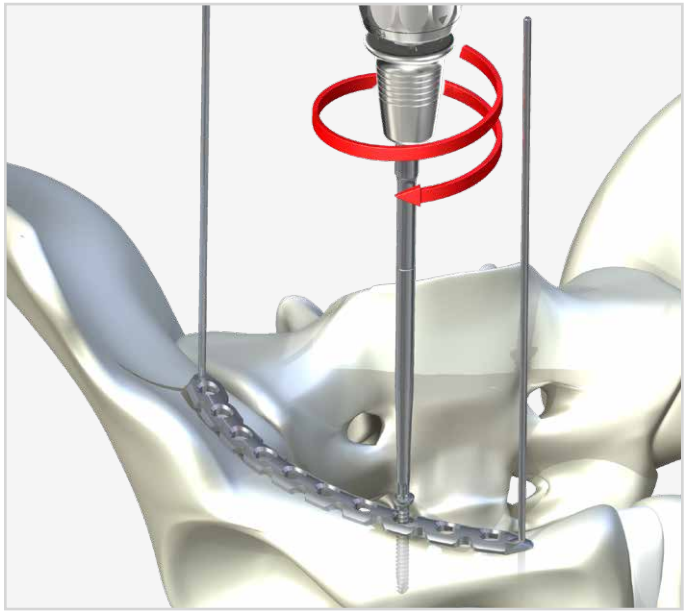
IV.3.3. Hole depth measurement

Insert the depth measure **[40.2667.100]** into the drilled hole until its hook reaches the outer surface of the other cortex.



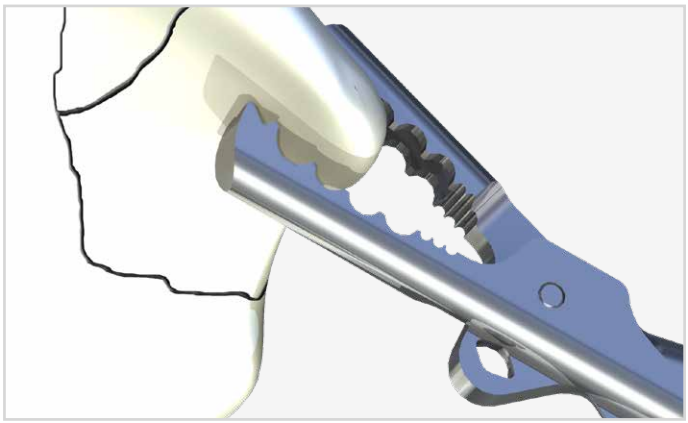
IV.3.4. Screw insertion

Insert cortical screw.

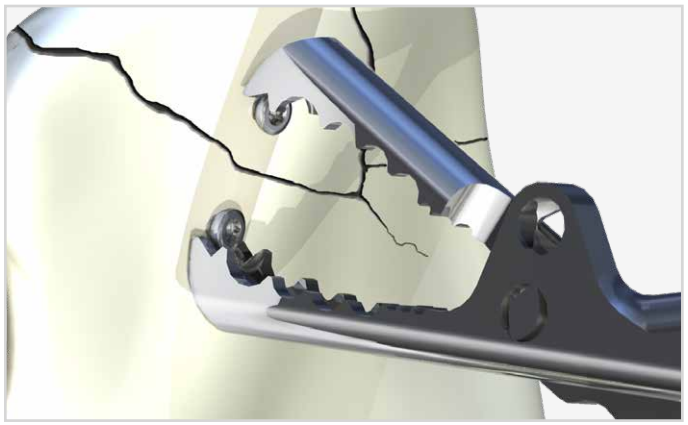


V. INSTRUMENTS FOR REDUCTION OF BONE FRAGMENTS

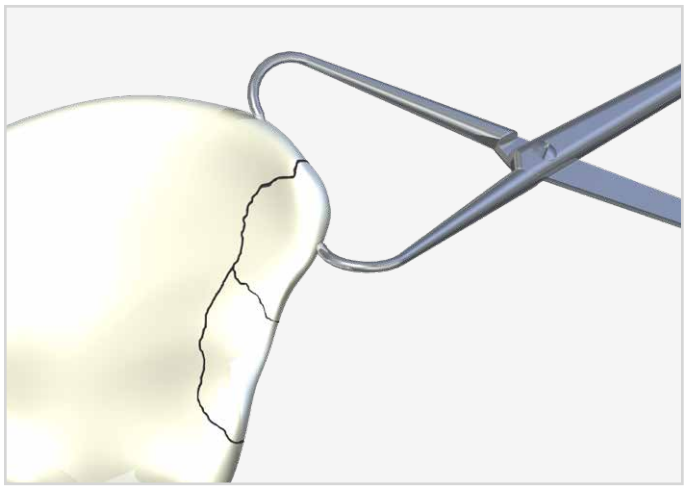
Forceps and other instruments used for fracture reduction are intended for irregular, large, flat and bony surface of the pelvic area.
Angles and the length of instruments are designed to accommodate spontaneous bone from crest to pelvic bridge and provide flexibility for a variety of surgical approaches.



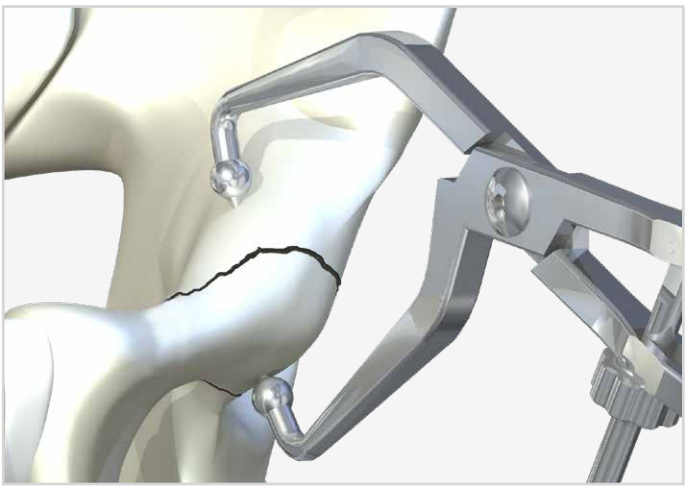
Compression forceps [40.6016.000] are a universal instrument which can be used to grasp and manipulate iliac wing, or may function as reduction forceps to reduce fractures with temporary cortical screws Ø3.5mm and Ø4.5mm.



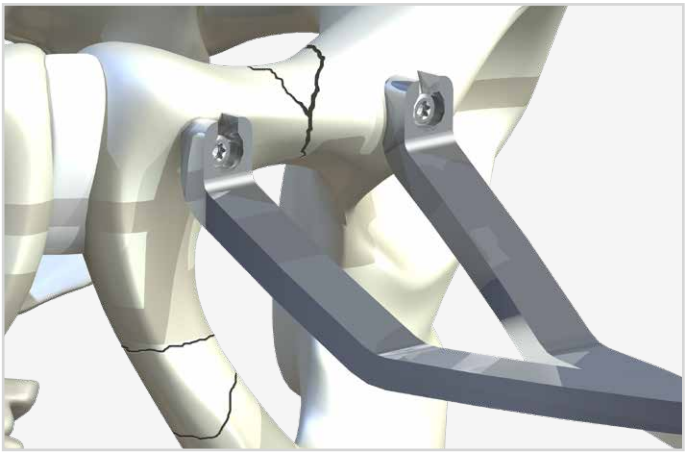
Reduction ratchet pliers with sharp tips [40.6009.000] may be used directly or after drilling shallow holes into the surface of the bone.



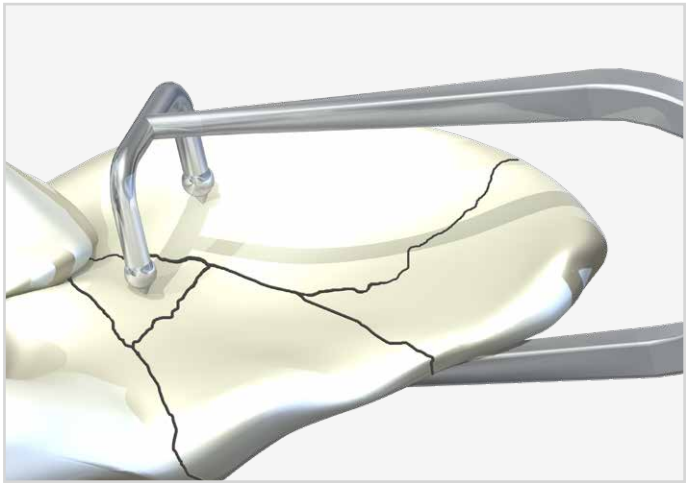
Angular reduction straight forceps [40.6006.000], **Angular reduction curved forceps long [40.6004.000]** and **Angular reduction curved forceps short [40.6005.000]** are designed so that the angle of the handle is away from both the surgeon line and the nominal soft tissue structures. Sharp tips provide a secure grip on the surface of the pelvis, while balls prevent their penetration into the bone with a thin cortex.



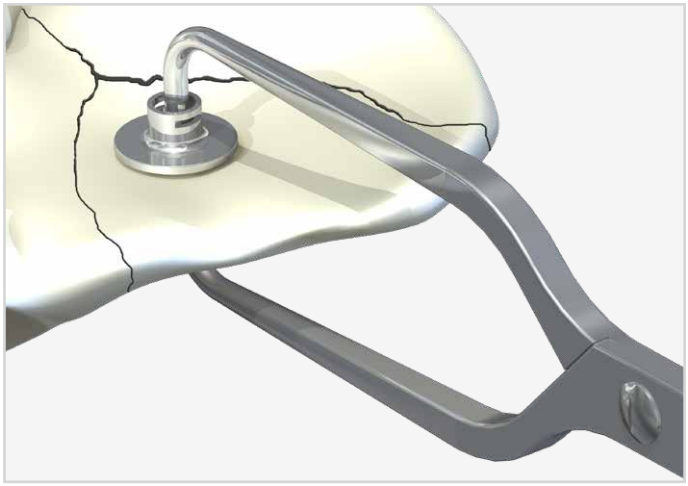
Reduction regulating forceps [40.6015.000] are intended for use with temporary cortical screws Ø3.5mm and Ø4.5mm. Screws inserted in the opposite side of the fracture allow for the creation of significant reduction forces and manipulation in all three planes.



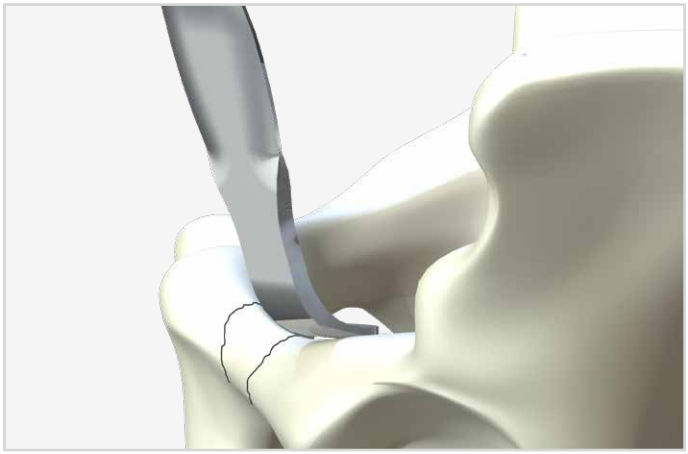
Reduction long forceps 2x1 [40.6008.000].
These forceps with three support points in the shape of balls allow for the reduction of perpendicular *(vertical)* fractures. The long handle provides increased lever system for difficult fractures.
Reduction long forceps are also available in 1x1 version **[40.6007.000]**.



Latch swinging round [40.6028.000].
Latch swinging rectangular [40.6029.000].
These instruments are used as controllers for forceps with round tips to reduce the fractured bone. The latch can be attached to the round tips to spread the reduction forces on the increased surface.



Elevator 24 [40.2199.001] can be used to improve the soft tissue widening.



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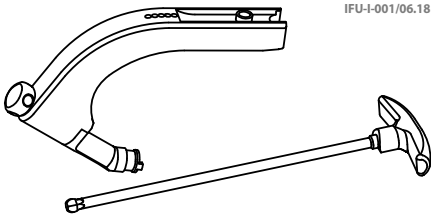
IFU-I-001/06.18



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

4.Devices made of aluminium 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 aluminium surface, shall be avoided.

5.Devices produced of plastics are mainly stands, palettes, cuvettes and some parts of instruments such as e.g. handles. Plastics used in the manufacture of instruments are mainly: PPSU *(Polyphenylsulfone)*, 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 consequences, 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 consequences, 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 medical 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® MediClean 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® MediClean 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-h 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 cannulated 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 - disinfector.
a) Equipment and materials: a washer - disinfector, 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 of washing 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 demineralised 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:
b) Holes, grooves and gaps the debris could have been pressed into during use.
a) Places where dirt can be found, such as joints, latches, etc.
3) Generally unmagnified visual inspection under good light conditions is sufficient.
4) 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, peels, etc.)*.
5) Damaged or defective product cannot be approved for further use.
6) 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 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 all 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**

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

	Do not reuse • Nie używać powtórnie • Не использовать повторно • No reutilizar • Nicht wiederverwenden • Nepoužívejte opakovaně • Non riutilizzare
STERILIZE	Do not resterilize • Nie sterylizować ponownie • Не стерилизовать повторно • No reesterilizar • Nicht resterilisieren • Nepoužívejte resterilizaci • Non risterilizzare
	Do not use if package is damaged • Nie używać jeśli opakowanie jest uszkodzone • Не использовать при поврежденной упаковке • No utilizar si el envace está dañado • Nicht verwenden falls Verpackung beschädigt ist • Nepoužívejte, pokud je obal poškozen • Non utilizzare se la confezione é danneggiata
	Consult Instructions for Use • Zajrzyj do instrukcji używania • Обратитесь к инструкции по применению • Consultar instrucciones de uso • Siehe die Gebrauchsanweisung • Řiďte se návodem k použití • Consultare le instruzioni per l'uso
NON STERILE	Non-sterile • Niesterylny • Не стерильно • No estéril • Unsteril • Nesterilní • Non sterile
	Caution • Ostrzeżenie • Осторожно • Advertencia • Vorsicht • Varování • Avvertenza
STERILE R	Sterilized using irradiation • Sterylizowany przez napromieniowanie • Радиационная стерилизация • Esterilizado mediante radiación • Sterilisiert durch Bestrahlung • Sterilizovat zářením • Sterilizzato mediante irradiazione
STERILE VH2O2	Sterilized using hydrogen peroxide • Sterylizowany nadtlenkiem wodoru • Стерилизован перекисью водорода • Esterilizado con peróxido de hidrógeno • Sterilisiert mit Wasserstoffperoxid • Sterilizováno s peroxidem vodíku • Sterilizzato mediante perossido di idrogeno
REF	Catalogue number • Numer katalogowy • Номер по каталогу • Número de catálogo • Katalognummer • Katalogové číslo • Numero di catalogo
LOT	Batch code • Kod partii • Код партии • Código de lote • Chargennummer • Číslo šarže • Codice del lotto
Mat:	Material • Materiał • Материал • Material • Materiál • Materiál • Materiale
Qty:	Quantity • Ilość • Количество • Cantidad • Menge • Množství • Quantita'
	Use by • Użyć do • Использовать до • Usar antes de • Verwenden bis • Použijte do • Da utilizzare entro il

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