Cannulated Pediatric Osteotomy System (CAPOS)

A single system of osteotomy blade plates and cannulated instrumentation

Surgical Technique







wlmage intensifier control

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Processing, Reprocessing, Care and Maintenance

For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:

http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance For general information about reprocessing, care and maintenance of DePuy Synthes reusable devices, instrument trays and cases, as well as processing of DePuy Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to: http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

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▲ Precautions

Cannulated Pediatric Osteotomy System (CAPOS)

The Cannulated Pediatric Osteotomy System (CAPOS) combines implants and instruments in one system. Cannulated instruments work over a guide wire for precise placement and safety.

Osteotomy plates are offered in a variety of sizes: infant, toddler, child, adolescent and small stature adult patients. Two graphic cases provide organization and storage for the complete system.



Please refer to the corresponding Instructions for Use for specific information on Intended use, Indications, Contraindications, Warnings and Precautions, Potential Adverse Events, Undesirable Side Effect and Residual Risks. Instruction for Use are available atwww.e-ifu.com and/or www.depuysynthes.com/ifu

The AO Principles of Fracture Management

Mission

The AO's mission is promoting excellence in patient care and outcomes in trauma and musculoskeletal disorders.

AO Principles^{1,2}

1.



Fracture reduction and fixation to restore anatomical relationships.

2.



Fracture fixation providing absolute or relative stability, as required by the "personality" of the fracture, the patient, and the injury.

3.



Preservation of the blood supply to soft-tissues and bone by gentle reduction techniques and careful handling. 4.



Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.

¹ Müller ME, Allgöwer M, Schneider R, Willenegger H. Manual of Internal Fixation. 3rd ed. Berlin, Heidelberg New York: Springer 1991.

² Buckley RE, Moran CG, Apivatthakakul T. AO Principles of Fracture Management: 3rd ed. Vol. 1: Principles, Vol. 2: Specific fractures. Thieme; 2017.

Preoperative Planning

1. Preoperative planning

Determine the appropriate osteotomy plate by blade length, angle, and displacement. Note the corresponding guide wire diameter.

■ Note:

The technique described in this guide is for a varus derotational osteotomy of the proximal femur, utilizing a 90° osteotomy blade plate. Steps may differ for alternative osteotomy techniques or fracture repair.

2. Position the patient

Surgery is typically performed on a radiolucent operating table. Position the patient for AP views of the hip under image intensification. Obtain lateral views of the hip by flexing and abducting the leg.

3. Surgical approach

Use a standard lateral approach to the proximal femur.

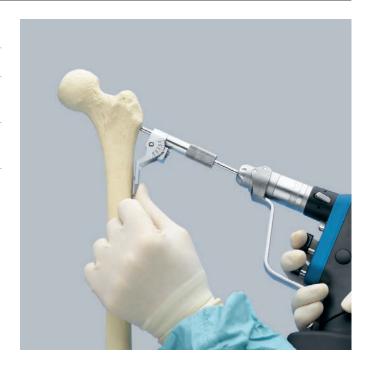
Place Guide Wire

4. Place guide wire

Instruments		
314.070	Screwdriver, hexagonal, small, Ø 2.5 mm, with Groove	
333.683	Adjustable Wire Guide, for Guide Wires 1.6 to 2.0 mm	

Make sure to locate trochanteric and femur head epiphysis. A guide wire may be held on the anterior side of the femoral neck to assist in determination of the direction that the position of the definitive guide wire will take.

Set the adjustable wire guide to the angle determined in the preoperative plan, using the small hexagonal screwdriver. For example, if a 30° varus osteotomy is planned, using a 90° osteotomy plate, then the adjustable wire guide should be set at 120° (=30°+90°).



Choose the guide wire that corresponds with the cannulated chisel and osteotomy plate selected.

Implant Size	Guide Wire	Direct Measuring Device	Cannulated Seating Chisel	Guide for Oscillating Saw
Infant Hip Plate	292.722 (1.6 mm) or 292.720 (1.6 mm)	319.170	332.173	332.356
Child Hip Plate 3.5 (Toddler)	292.652 (2.0 mm) or 292.650 (2.0 mm)	319.210	332.174	332.355
Child Hip Plate 4.5 and Hip Plate 4.5 (Adolescent and/ or small stature adults)	292.652 (2.0 mm) or 292.650 (2.0 mm)	319.210	332.175	332.354

Load the guide wire through the adjustable wire guide. Insert the wire into the femoral neck (Figures 1, 2 and 3a). Optimal placement of the guide wire is inferior in the neck, above the calcar region as seen in the AP view. In the lateral view, the guide wire should be located centrally in the femoral neck. The guide wire should not penetrate the epiphysis of the femur head.

Verify final placement of the guide wire in both views, under image intensification (Figure 3b).

■ Note:

Be aware that marginal placement of the guide wire could cause the chisel and osteotomy plate to penetrate the medial, anterior or posterior cortex.



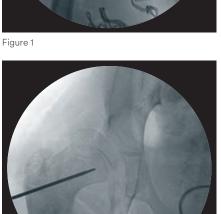


Figure 3a



Figure 2

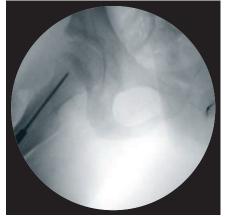


Figure 3b

5. Measure depth of guide wire

Instruments 319.170 Direct Measuring Device for Cannulated Screws Ø 4.5 mm or 319.210 Direct Measuring Device for Cannulated Screws Ø 7.0 mm

Slide the appropriate direct measuring device over the guide wire. Determine and record the insertion depth of the guide wire. This measurement is critical in determining appropriate chisel insertion in the next step. The proper blade length of the osteotomy plate will typically be the next size smaller than the measurement taken with the direct measuring device.



Position Chisel

6. Position chisel

Chisel Guide, with adjustable angle
Seating Chisel, cannulated, ∅ 1.6 mm, for Infant Hip Plates 3.5
Seating Chisel, cannulated, Ø 2.0 mm, for Child Hip Plates 3.5
Seating Chisel, cannulated, Ø 2.0 mm, for Child Hip Plates 4.5 and for Hip Plates 90°

Place the cannulated chisel in the chisel guide and over the guide wire. The chisel and chisel guide assembly can be rotated in the anterior or posterior direction to achieve flexion or extension, respectively. Should a neutral position be desired, the chisel guide should align with the femoral shaft.

Anterior angulation = flexion at the osteotomy site Posterior angulation = extension at the osteotomy site





Neutral



Flexion



Extension

Insert Chisel

7. Insert chisel

Instruments	
319.170	Direct Measuring Device for Cannulated Screws Ø 4.5 mm
or	
319.210	Direct Measuring Device for Cannulated Screws Ø 7.0 mm
399.420	Hammer 500 g

Correct insertion depth can be calculated by taking the measurement obtained with the direct measuring device and subtracting the osteotomy plate blade length. This figure should correspond with the appropriate chisel insertion depth as measured by the calibrated window of the chisel.

■ Note:

Direct Measuring Device (DMD) measurement (see step 5) minus implant blade length equals insertion measurement on chisel window (see example).

Use the hammer to drive the cannulated chisel along the guide wire and into the femoral neck.

▲ Precaution:

During hammering of the chisel, take care to keep the chisel properly tracking over the guide wire and avoid any bending force on the wire.

It may be required to intermittently withdraw the chisel during the insertion.



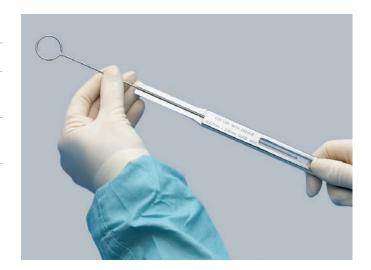
Example:

- 44 mm (DMD measurement)
- 38 mm (implant blade length)
- = 6 mr

Cleaning Tip

Instruments		
319.350	Cleaning Stylet Ø 1.6 mm, for Cannulated Instruments	
319.360	Cleaning Stylet Ø 2.0 mm, for Cannulated Instruments	

Cleaning the cannulation of the chisels is imperative to prevent accumulation of debris. Instruments can be cleaned intraoperatively using the cleaning stylets.

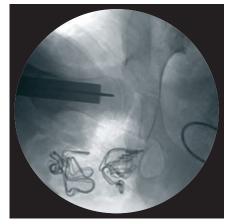


During chisel insertion verify proper tracking over the guide wire by periodically checking progress with image intensification.

Monitor insertion depth by observing the position of the guide wire in the calibrated window of the chisel. Stop insertion once the predetermined insertion measurement is achieved.







Confirm proper chisel placement under image intensification

Perform Osteotomy

8. Perform osteotomy

Instruments	
332.173	Seating Chisel, cannulated, ∅ 1.6 mm, for Infant Hip Plates 3.5
332.174	Seating Chisel, cannulated, Ø 2.0 mm, for Child Hip Plates 3.5
332.175	Seating Chisel, cannulated, Ø 2.0 mm, for Child Hip Plates 4.5 and for Hip Plates 90°
332.200	Slotted Hammer
332.354	Guide for Oscillating Saw, for Child Hip Plates 4.5 and for Hip Plates 90°
332.355	Guide for Oscillating Saw, for Child Hip Plates 3.5
or	
332.356	Guide for Oscillating Saw, for Infant Hip Plates 3.5

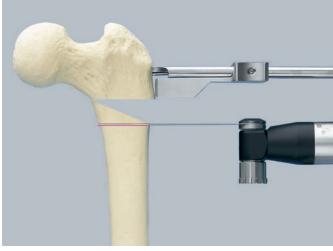
Before beginning the osteotomy, ensure that the chisel is loosened slightly, with a reverse impact with the slotted hammer.

In case of a planned rotation osteotomy, control rotation with insertion of guide wires above and below the osteotomy site in a manner that will not interfere with plate placement. This method is recommended for other correction as well to guarantee the right position of the two bone fragments. Pull the medial soft tissues aside with retractors.

Slide the appropriate guide for oscillating saw on the inferior side of the cannulated chisel. Through image intensification verify the correct position of the superior cut that should be below the level of the femoral neck. Using appropriate power equipment and saw, perform the first osteotomy cut parallel to the saw guide, respectively oblique to the femur shaft.



Perform the first osteotomy cut parallel to the saw guide.



Make the second cut starting at the same point, but directed perpendicular to the femoral shaft.

Using the cannulated chisel as a lever, carefully tilt the proximal bone fragment to the desired position. Make the second cut starting at the same point on the lateral cortex, but directed perpendicular to the femoral shaft. Remove the wedge of bone from the distal segment of the femur.

The same technique, but with inverse cuts can be performed. The first cut is made perpendicular to the femur shaft, whereas the second cut is oblique, resulting in a wedge as described above.

▲ Precaution:

When the saw guide is used, exercise caution to prevent saw penetration into the femoral neck.

■ Note:

In some cases, particularly of neuromuscular disease, the bone may be soft. This osteotomy technique will result in a shortening of the total length of the femur, but may minimize extensive muscular traction forces.

Alternative technique

The technique described thereafter does not cause femoral shortening. Only one osteotomy cut is performed. The osteotomy should be made perpendicular to the femoral shaft, 10 mm distal to the entry side of the position wire. The guide of the oscillating saw can be used as a distance marker in this case. Therefore, this technique is only recommended for very experienced specialists.

Insert Plate

9. Insert Plate

Instruments		
321.200	Ratchet Wrench for Nut, hexagonal, 11.0 mm	
332.210	Impactor, for Angled Blade Plates	
332.352 or	Inserter/Extractor, for Child Hip Plates	
332.353	Inserter/Extractor for Child Hip Plates 4.5 and for Hip Plates 90°	
333.060	Positioning Plate, triangular, 90°/50°/40°	
333.070 or	Positioning Plate, triangular, 80°/70°/30°	
333.080	Positioning Plate, triangular, 100°/60°/20°	
398.811	Plate Holding Forceps, with Swivel Foot, size 0	
398.813	Plate Holding Forceps, with Swivel Foot, size 2	

Carefully remove the cannulated chisel, saw guide, and guide wire.



Insert the osteotomy plate.



The impactor is used for final insertion of the plate.

Insert the selected osteotomy plate by hand, ensuring that the plate follows the path created by the chisel. It is best to avoid using a hammer during initial insertion, so that one can feel the plate tracking properly along the chisel path. Verify with image intensification that the plate is following the chisel track.

After the plate has been inserted sufficiently, affix the proper inserter/extractor and tighten with the ratchet wrench. This will provide control of the proximal fragment. Continue insertion using the hammer.

Reduce the proximal and distal segments. Provisionally clamp the distal segment to the plate, using plate holding forceps. Check varus, flexion, and extension alignment. Remove the inserter/extractor. Use the impactor to completely insert the plate into the femoral neck.

Use the previously placed guide wires to adjust rotation. Normal anteversion is approximately 20°, but other anteversion values may be appropriate. The triangular positioning plates can be used to measure rotation.

Examine osteotomy alignment with image intensification.

Secure Plate

10. Secure plate

Secure the plate to the femoral shaft using standard DCP screw insertion technique, selecting the appropriate size cortex screws.

The final result should be verified with AP and lateral views.

Implant Removal

Instruments

332.352 or	Inserter/Extractor, for Child Hip Plates
332.353	Inserter/Extractor for Child Hip Plates 4.5 and for Hip Plates 90°
332.200	Slotted Hammer
321.200	Ratchet Wrench for Nut, hexagonal, 11.0 mm

Loosen all screws from the plate, then remove the screws completely from the bone. This prevents simultaneous rotation of the plate when unlocking the last screw. Attach the Inserter/Extractor Handle as for insertion and remove the plate using the Slotted Hammer.

If a screw cannot be removed with the screwdriver, refer to the Surgical Technique "Screw Extraction Set".



332.352 and plate



332.353 and plate

Selected Instruments from CAPOS Instrument Set

319.350	Cleaning Stylet Ø 1.6 mm, for Cannulated Instruments	
319.360	Cleaning Stylet Ø 2.0 mm, for Cannulated Instruments	
332.090	Chisel Guide, with adjustable angle	
332.173	Seating Chisel, cannulated, Ø 1.6 mm, for Infant Hip Plates 3.5 (Infant)	DIFANT CHISEL I I I I I I I I I I I I I I I I I I I
332.174	Seating Chisel, cannulated, Ø 2.0 mm, for Child Hip Plates 3.5 (Toddler)	TOODLER CHISEL # 2.0mm i 200mm CUDE WRE # 8 8
332.175	Seating Chisel, cannulated, Ø 2.0 mm, for Child Hip Plates 4.5 and for Hip Plates 90° (Adolescent)	CHIED AND ADOLESCENT CHEEL # 2.0mm : 200mm GUCE WARE \$ 5 8 8

332.210	Impactor, for Angled Blade Plates	0	>-
332.352	Inserter/Extractor, for Child Hip Plates 3.5	FOR TODOLER, INFANT AND INFURCATED PLATES	
332.353	Inserter/Extractor, for Child Hip Plates 4.5 and for Hip Plates 90° (Adolescent)	ASSERTER-CHILD, AND, ADOLESS	CENT PLATES
332.354	Guide for Oscillating Saw, for Child Hip Plates 4.5 and for Hip Plates 90°	Have audie Adolested Processed Proce	Side
332.355	Guide for Oscillating Saw, for Child (Toddler) Hip Plates 3.5	Rottom	Side
332.356	Guide for Oscillating Saw, for Infant Hip Plates 3.5	Pottom	Side

333.060	Positioning Plate, triangular, 90°/50°/40°	90
333.070	Positioning Plate, triangular, 80°/70°/30°	30 70
333.080	Positioning Plate, triangular, 100°/60°/20°	20
333.683	Adjustable Wire Guide, for 1.6 mm to 2.0 mm Guide Wires	

Cannulated Pediatric Osteotomy System (CAPOS) Instrument Set

Graphic Case

690.364 Graphic Case for Instruments for

Cannulated Paediatric Osteotomy Sys-

tem (CAPOS)

mstruments	
292.200.01	Kirschner Wire \varnothing 2.0 mm with trocar tip,
	length 150 mm, Stainless Steel
292.650	Guide Wire ∅ 2.0 mm with threaded tip
	with trocar, length 230 mm, Stainless
	Steel
292.652	Guide Wire ∅ 2.0 mm with spade point
	tip, length 230 mm, Stainless Steel
292.720	Guide Wire ∅ 1.6 mm with threaded tip
	with trocar, length 150 mm, Stainless
	Steel
292.722	Guide Wire Ø 1.6 mm with spade point
	1. 1. 1. 4.0.

tip, length 150 mm

310.250 Drill Bit Ø 2.5 mm, length 110/85 mm,

2-flute, for Quick Coupling

310.310 Drill Bit Ø 3.2 mm, length 145/120 mm,

2-flute, for Quick Coupling

311.320 Tap for Cortex Screws Ø 3.5 mm,

length 110/50 mm

311.440 T-Handle with Quick Coupling

311.460 Tap for Cortex Screws Ø 4.5 mm,

length 125/70 mm

312.200 Triple Drill Guide 2.0, with 3 holes 314.030 Screwdriver Shaft, hexagonal, small,

 \emptyset 2.5 mm

314.070 Screwdriver, hexagonal, small, Ø

2.5 mm, with Groove

Holding Sleeve, for Nos. 314.070, 314.090

314.550 and 314.570

314.110 Holding Sleeve, large

314.150 Screwdriver Shaft, hexagonal, large,

314.270 Screwdriver, hexagonal, large, ∅

3.5 mm, with Groove, length 245 mm

319.040 Depth Gauge for Screws, measuring

range up to 50 mm

319.100 Depth Gauge for Screws Ø 4.5 to

6.5 mm, measuring range up to 110 mm

Direct Measuring Device for Cannulated 319.170

Screws Ø 4.5 mm

319.210 Direct Measuring Device for Cannulated

Screws Ø 7.0 mm



Instruments		Also Available	
319.350	Cleaning Stylet ∅ 1.6 mm, for Cannulated Instruments	332.190	Seating Chisel, length 260 mm, T-profile for Angled Blade Plates
319.360	Cleaning Stylet ∅ 2.0 mm, for Cannulated Instruments	398.811	Plate Holding Forceps, with Swivel Foot, size 0
321.120	Tension Device, articulated, span 20 mm	398.813	Plate Holding Forceps, with Swivel Foot,
321.200	Ratchet Wrench for Nut, hexagonal, 11.0 mm		size 2
323.360	Universal Drill Guide 3.5		
323.460	Universal Drill Guide 4.5/3.2, for neutral and load position		
332.090	Chisel Guide, with adjustable angle		
332.173	Seating Chisel, cannulated, ∅ 1.6 mm, for Infant Hip Plates 3.5		
332.174	Seating Chisel, cannulated, ∅ 2.0 mm, for Child Hip Plates 3.5		
332.175	Seating Chisel, cannulated, ∅ 2.0 mm, for Child Hip Plates 4.5 and for Hip Plates 90°		
332.200	Slotted Hammer		
332.210	Impactor, for Angled Blade Plates		
332.352	Inserter/Extractor, for Child Hip Plates		
332.353	Inserter/Extractor for Child Hip Plates 4.5 and for Hip Plates 90°		
332.354	Guide for Oscillating Saw, for Child Hip Plates 4.5 and for Hip Plates 90°		
332.355	Guide for Oscillating Saw, for Child Hip Plates 3.5		
332.356	Guide for Oscillating Saw, for Infant Hip Plates 3.5		
333.060	Positioning Plate, triangular, 90°/50°/40°		
333.070	Positioning Plate, triangular, 80°/70°/30°		
333.080	Positioning Plate, triangular, 100°/60°/20°		
333.683	Adjustable Wire Guide, for Guide Wires 1.6 to 2.0 mm		
359.204	Pliers, flat-nosed, for TEN		
399.420	Hammer 500 g		

Cannulated Pediatric Osteotomy System (CAPOS) Implant Set

Graphic Cases and Trays Instrumentation Case

60.108.010 Graphic Case for Implants for Cannu-

lated Pediatric Osteotomy System in

Children

The implant graphic case consists of three levels:

Bottom: additional implants
Middle tray: implants 3.5
Top tray: implants 4.5

Implants

3.5 mm Cortex Screws, self-tapping, 8 ea.

	Length	
204.814	14 mm	
204.816	16 mm	
204.818	18 mm	
204.820	20 mm	
204.822	22 mm	
204.824	24 mm	
204.826	26 mm	
204.828	28 mm	
204.830	30 mm	

Mini Infant Hip Plate 115°

	Blade Length	Displacement
236.400	30 mm	5 mm
236.430	35 mm	5 mm

Infant Hip Plate 3.5, 90°

•	· ·	
	Blade Length	Displacement
236.250	25 mm	7 mm
236.260	32 mm	7 mm
236.350	25 mm	12 mm
236.360	32 mm	12 mm

Child Hip Plate 3.5, 90°

	Blade Length	Displacement
236.001	26 mm	4 mm
236.002	32 mm	4 mm
236.011	26 mm	8 mm
236.012	32 mm	8 mm
236.013	38 mm	8 mm



Cannulated Pediatric Osteotomy System, Container 1: Mini Infant, Infant and Child/Toddler Implant Tray including 3.5 Cortex Screw rack

Implants

Osteotomy Plate 100° (Child Hip Plate 3.5/Toddler)

	Blade Length	Displacement
236.101*	26 mm	4 mm
236.102*	32 mm	4 mm
236.103*	38 mm	4 mm
236.104*	44 mm	4 mm
236.111*	26 mm	8 mm
236.112*	32 mm	8 mm
236.113*	38 mm	8 mm
236.114*	44 mm	8 mm

^{*} Those Osteotomy plates 100° are only available non-sterile.

Implants

4.5 mm Cortex Screw, self-tapping**

	Length	
214.816	16 mm	
214.818	18 mm	
214.820	20 mm	
214.822	22 mm	
214.824	24 mm	
214.826	26 mm	
214.828	28 mm	
214.830	30 mm	
214.832	32 mm	

Child Hip Plate 4.5, 80°

	Blade Length	Displacement
235.170	35 mm	8 mm
235.190	45 mm	8 mm

Child Hip Plate 4.5, 90°

	Blade Length	Displacement
235.270	35 mm	8 mm
235.290	45 mm	8 mm

Child Hip Plate 4.5, 100°

	Blade Length	Displacement
235.370	35 mm	8 mm
235.390*	45 mm	8 mm

^{*} Those plates are only available non-sterile.

All other plates without * are available sterile packed. For sterile implants add suffix "S" to article numbers (e.g. 214.816S).



Cannulated Pediatric Osteotomy System, Container 2: Child Implant Tray including 4.5 Cortex Screw rack

^{**}Add suffix "S" and "TS" to product number to order sterile product.

Implants

Hip Plate 90° (Adolescent)

	Blade Length	Displacement
235.600	50 mm	10 mm
235.680	40 mm	10 mm
235.700	50 mm	15 mm
235.720	60 mm	15 mm
235.780	40 mm	15 mm

All plates 90° are available sterile packed. For sterile implants add suffix "S" to article numbers (e.g. 235.600S).

Hip Plate 100° (Adolescent)

	Blade Length	Displacement 10 mm	
235.601*	50 mm		
235.681*	40 mm	10 mm	
235.701*	50 mm	15 mm	
235.721* 60 mm 15		15 mm	
235.781*	40 mm	15 mm	

^{*} The Hip plates 100° are only available non-sterile.

Implants also available

95° Condyla	r Plates, 5 holes			
	Blade Length	Displacement		
282.500	50 mm	92 mm		
282.520	60 mm	92 mm		
282.540	70 mm	92 mm		
282.580	40 mm	92 mm		
95° Condyla	r Plates, 7 holes			
	Blade Length	Displacement		
282.700	50 mm	124 mm		
282.720	60 mm	124 mm		
282.740	70 mm	124 mm		
282.780	40 mm	124 mm		
95° Condyla	r Plates, 9 holes			
	Blade Length	Displacement		
282.900	50 mm	156 mm		
282.920	60 mm	156 mm		
282.940	70 mm	156 mm		
282.980	40 mm	156 mm		
130° Angled	Blade Plates, 4 holes*			
	Blade Length	Displacement		
283.400	50 mm	60 mm		
283.420	60 mm	60 mm		
283.440	70 mm	60 mm		
283.460	80 mm	60 mm		
All plates are -:-:	lable sterile peaked. For sterile in	aplanta add suffix "C" toti-l-		

283.600	50 mm	104 mm	
283.620	60 mm	104 mm	
283.640	70 mm	104 mm	
283.660	80 mm	104 mm	
130° Angled	Blade Plates, 9 holes*		
	Blade Length	Displacement	
283.900	50 mm	152 mm	
283.920	60 mm	152 mm	
283.940	70 mm	152 mm	

Displacement

152 mm

130° Angled Blade Plates, 6 holes*

283.960

Blade Length

80 mm

All plates are available sterile packed. For sterile implants add suffix "S" to article numbers (e.g. 282.500S).

^{*}Note: Seating chisel (332.190) is needed for use with these plates.

MRI Information

Torque, Displacement and Image Artifacts according to ASTM F2213, ASTM F2052 and ASTM F2119

Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.

Radio-Frequency-(RF-)induced heating according to ASTM F 2182

Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 6 minutes [1.5 T] and for 15 minutes [3 T]).

▲ Precautions:

The above mentioned test relies on non-clinical testing. The actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. Thus, it is recommended to pay particular attention to the following points:

- It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations.
- Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures.
- Generally, it is recommended to use a MR system with low field strength in the presence of conductive implants.
 The employed specific absorption rate (SAR) should be reduced as far as possible.
- Using the ventilation system may further contribute to reduce temperature increase in the body.

Not all products are currently available in all markets.

This publication is not intended for distribution in the USA.

Please refer to the corresponding Instructions for Use for specific information on Intended use, Indications,

Contraindications, Warnings and Precautions, Potential Adverse Events, Undesirable Side Effect and Residual Risks.

Instruction for Use are available at www.e-ifu.com and/or www.depuysynthes.com/ifu





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