





Cementless femoral components of total hip joint replacement

ARTHROPLASTY

Preface

The cementless cup of a total hip joint replacement type SF of the 2nd generation was designed using the latest knowledge and experience with cementless endoprostheses. It is made of titanium alloy and manufactured using latest technology by CNC-controlled machines for surfacing. Surface is conditioned with plasma coating of bioactive titanium oxide layer that ensures full biocompatibility of the implant. Instruments ensure easy implantation and thorough fixation. Wide size series available makes it possible to solve almost every case of first implantation. The cementless cup type SF of the 2nd generation is used in the first implantation of total hip joint replacement and is intended for biologically younger patients with good vitality and probability of good integration of the implant with bone tissue. Complete set of cementless total hip joint replacement consist of a femoral component (stem), a head and an acetabular component (cup). Set can be combined without limitation within the whole supplied size series. A head with 12/14 taper can be fixed on the stem. Diameter of head is determined by corresponding inside diameter of the articulation insert.

Characteristics of the implant:

- Perfectly prepared acetabulum
- Bioactive surface coating
- verified fast secondary fixation by osteointegration.
- Shell
 - shells can be perfectly fixed to the bottom of the acetabulum.
- Flat cup is intended for implantation to the dysplastic acetabulum

Indication

- Primary and secondary coxathrosis
- Idiophatic necrosis heads
- Inflammatory and after inflammatory conditions
- After accident conditions (pseudoarthrosis) of femoral neck
- Acetabulars fractures
- Some bone tumors, etc.



Cementless total hip joint replacement type SF of the 2nd generation

- Articulation surfaces: head ceramics, liner crosslinked UHMWPE
 reduction of abrasive wear and osteolysis limitation
- New PE-liner with twelve-edged profile
- easy insertion of the liner into the covering in its whole circumference
- Shorter stem, tapered in the proximal part
- can be used also in MIS surgeries

- Acetabular cup with fixation screws
- possibility of rotation-proof fixation
- Optimal set in price/performance ratio

SOLUTION FOR BIOLOGICALLY YOUNGER PATIENTS





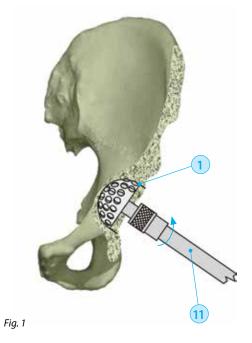
Surgical technique – cup

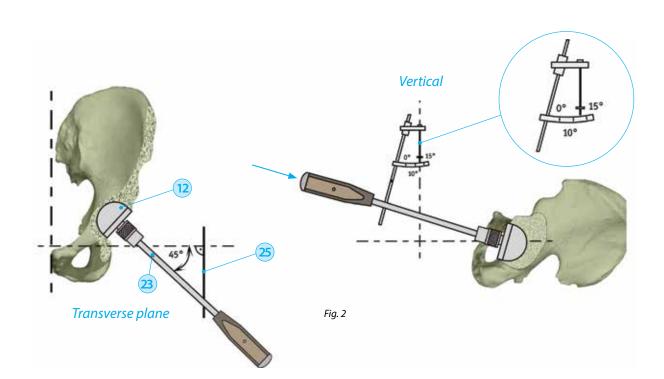
1. Preparation of the acetabulum

Acetabulum is drilled to the dimension determined with aid of a transparent pattern and the preoperative X-ray. Special acetabular reamers **1** are used clamped into adapter **11** (see Fig. 1). First, use a reamer of the same size as the original acetabulum. Gradually change to larger reamers at 2-mm intervals, until cartilage is completely removed. Hard subchondral bone underneath must be completely exposed. Upon preparing the acetabulum, remove remains of joint's socket and large osteophytes.

2. Control of prepared acetabulum

Control of the depth and diameter of prepared acetabulum is done with pattern 12 mounted on a quick mount holder 23 with a horizontal 25 and vertical 26 aiming shoulder and a protractor, (see Fig. 2). Edges of the pattern must correspond to bone edges of acetabulum so that non-cemented socket is completely covered.



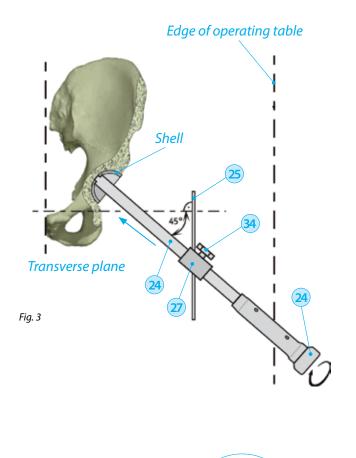


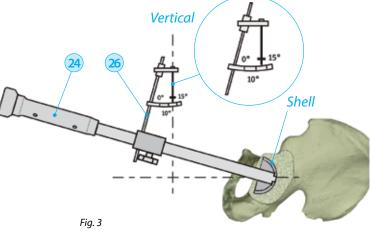
3. Implantation of the acetabular component - cup (Implantation of the socket coat)

Firstly, prepare the set for insertion of the implant. The metal coat of non-cemented socket, which must be 2-mm larger in diameter than the largest reamer used, is inserted into the acetabulum (24), by means of a holder, (see Fig. 3), with a horizontal 25 and vertical (26) shoulders and protractor. Coat is connected with guiding holder by setting oval end of the stem into the bottom of the coat and screwing the guiding holder into the threaded hole in the coat. Tighten connecting hexagonal screw in handle using a 5-mm hexagonal screwdriver. Screwdriver is inserted through the hole in stop lock of the handle (24) and turned clockwise. Before inserting socket, adjust operating table in a horizontal position. Socket must be turned transversally to 45° from the sagittal level: guiding holder (24) is set up using the horizontal shoulder **25**, which is positioned parallel with operating table and axis of the patient, (see Fig. 3). The second auxiliary should er (26) is then inserted vertically into the guiding holder. It has a simple protractor with a pendulum on its end. This protractor shows the size of socket's anteversion to the pelvis. In most cases, anteversion of 10° to 15° should be chosen.

For revision surgeries there are available shells with 10 or 12 holes with a specially designed screws L 20 mm, diameter 6.5 mm with thread up to the head. Metal coat surface must be in full contact with prepared acetabulum. A visual check whether the coat fits into the bottom of acetabulum can be made upon removing guiding holder through opening in the bottom of the coat. Socket coat is inserted by hammering the bumper of holder 24 in direction of arrow. If position of the metal coat is correct, close the opening with a threaded stopper. Make sure that the stopper does not protrude. This requirement must be met before inserting the articulated part.

Note: If using a coat with holes, make sure that it is turned in the right direction. Screws are inserted into the top of acetabulum. From this point onwards, inserted coat can no longer be turned.





Auxiliary fixation with screws – par. 4 and 5

This part applies only if coats with holes are used (type B3, B10 and B12)

4. Drilling of holes

If using coats with holes for screws, use a 3.2-mm drill with a flexible extension 30, (see Fig. 4), and a drilling coat 27 set for the 3.2 hole. Using a special depth gauge 34, measure the depth of holes – scale of the gauge will show the right length of screws. If a 3-hole coat is used, turn the holes towards the top of the acetabulum to make the fixation.

5. Insertion of screws

For cancellous screw L 20 mm, diameter 6.5 mm we drill holes with 4 mm drill. This is a specially modified screw with thread up to the head.

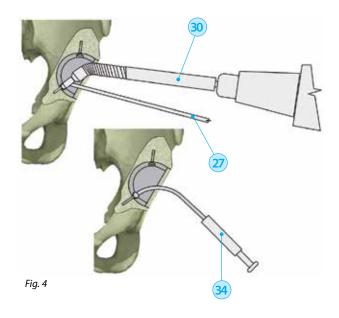
Fasten the cortical or cancellous flat-head screws with the aid of special pliers 35 and screw them in using a 3.5-mm hexagonal screwdriver 36. It is necessary to tighten the screws properly, because if heads of badly tightened screws stick out, the polyethylene articulated insert and the safety wire of the coat will not fit properly.

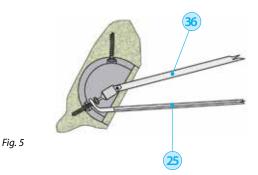


For stable position and fixation of the coat it is necessary to properly insert and tighten up all screws (par. 3). Inadequate fixation will allow micro-movement between the coat and the screws and may damage the articulated insert.

6. Trial fitting

Insert the trial polyethylene implant (37) into the coat, (see Fig. 6). It does not need to be fastened as it is held by the flexible safety wire.





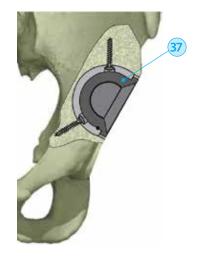


Fig. 6

7. Insertion of the articulated insert

Before final insertion of the polyethylene articulated insert, (see Fig. 7), make sure that the safety wire of metal coat is functioning properly.

If the position is correct, insertion of articulated insert will be accompanied by the sound of a click. Check contact of both components with the aid of a small raspator.

Cementless cup type SF

Diameter of milling cutter and template (mm)	Diameter of shell (mm)
38	40
40	42
42	44
44	46
46	48
48	50
50	52
52	54
54	56
56	58
60	62
62	64
64	66
66	68

Instrumentation set

Instrumentation set is stored in three trays (order number of set 301020) with the possibility to add additional 2 sets (order numbers: – see page 12, 300020 – see page 14) allowing clear arrangement of instruments not only during transport, storage and preparation, but also during operations. Instruments layout in trays is on the following figs, numerical marking of instruments correspond with images in the surgical manual. During transportation trays are placed in a container that allows sterilization.

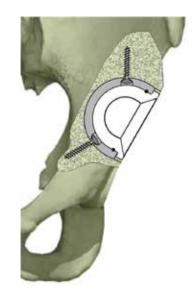


Fig. 7

The set of instruments - 301020



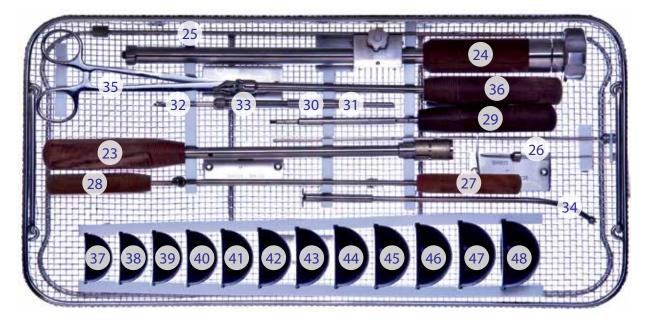
Instruments for application of cementless cup type SF LAY-OUT - TRAY I.

	Denomination	Qty	Order number	
	Box I. for application of cementless acetabular cup SF	1	301022	
1	Acetabular reamer with self-locking connection, \varnothing 44 (mm)	1	304625	
2	Acetabular reamer with self-locking connection, \varnothing 46 (mm)	1	304635	
3	Acetabular reamer with self-locking connection, \varnothing 48 (mm)	1	304640	
4	Acetabular reamer with self-locking connection, \varnothing 50 (mm)	1	304645	
5	Acetabular reamer with self-locking connection, \varnothing 52 (mm)	1	304650	
6	Acetabular reamer with self-locking connection, \varnothing 54 (mm)	1	304655	
7	Acetabular reamer with self-locking connection, \varnothing 56 (mm)	1	304665	
8	Acetabular reamer with self-locking connection, \varnothing 58 (mm)	1	304670	
9	Acetabular reamer with self-locking connection, \varnothing 60 (mm)	1	304675	
10	Acetabular reamer with self-locking connection, \varnothing 62 (mm)	1	304680	
11	Adjustable acetabular reamer-triangular connection	1	304102	
12	Acetabular cup template, diameter, $arnothing$ 44 (mm)	1	304825	
13	Acetabular cup template, diameter, $arnothing$ 46 (mm)	1	304835	
14	Acetabular cup template, diameter, $arnothing$ 48 (mm)	1	304840	
15	Acetabular cup template, diameter, $arnothing$ 50 (mm)	1	304845	
16	Acetabular cup template, diameter, $arnothing$ 52 (mm)	1	304850	
17	Acetabular cup template, diameter, $arnothing$ 54 (mm)	1	304855	
18	Acetabular cup template, diameter, $arnothing$ 56 (mm)	1	304865	
19	Acetabular cup template, diameter, $arnothing$ 58 (mm)	1	304870	
20	Acetabular cup template, diameter, $arnothing$ 60 (mm)	1	304875	
21	Acetabular cup template, diameter, $arnothing$ 62 (mm)	1	304880	
22	Acetabular cup cover extractor type SF	1	304160	

The cassette lay out has only an informative character and may be amended depending on inovation changes carried out.

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The set of instruments - 301020

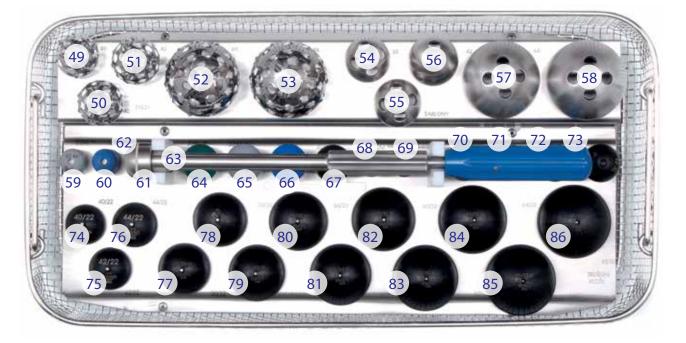


Instruments for application of cementless cup type SF LAY-OUT - TRAY II.

	Denomination	Qty	Order number
	Box II. application for cementless acetabular cup SF	1	301024
23	Handle for acetabular cup templates	1	304800
24	Acetabular cup cover inserting instrument SF	1	304100
25	Horizontal alignment rod for acetabular cup	1	304930
26	Vertical alignment rod for acetabular cup	1	304935
27	Drill guide 3,2 for acetabular cup SF	1	304115
28	Drill guide 4,0 for acetabular cup SF	1	304116
29	Hexagonal screwdriver 3,5 mm	1	102450
30	Flexible adapter for exchangeable drill bit 3,2/triang.	1	403051
31	Flexible adapter for exchangeable drill bit 4,0/triang.	1	403052
32	Exchangeable drill bit 3,2-65/35	1	403063
33	Exchangeable drill bit 4-65/35	1	403067
34	Depth gauge for cementless acetabular cup SF	1	304120
35	Holding pliers for cementless acetabular cup SF	1	304122
36	Articulated screwdriver	1	304125
37	Trial surface $arnothing$ 46 mm for cementless acetabular cup SF	1	304130
38	Trial surface \varnothing 48 mm for cementless acetabular cup SF	1	304132
39	Trial surface $arnothing$ 50 mm for cementless acetabular cup SF	1	304134
40	Trial surface \varnothing 52 mm for cementless acetabular cup SF	1	304136
41	Trial surface $arnothing$ 54 mm for cementless acetabular cup SF	1	304138
42	Trial surface $arnothing$ 56 mm for cementless acetabular cup SF	1	304140
43	Trial surface $arnothing$ 58 mm for cementless acetabular cup SF	1	304142
44	Trial surface $arnothing$ 60 mm for cementless acetabular cup SF	1	304144
45	Trial surface $arnothing$ 62 mm for cementless acetabular cup SF	1	304146
46	Trial surface $arnothing$ 64 mm for cementless acetabular cup SF	1	304148
47	Trial surface $arnothing$ 66 mm for cementless acetabular cup SF	1	304150
48	Trial surface $arnothing$ 68 mm for cementless acetabular cup SF	1	304152

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The set of instruments - 301020



Instruments for application of cementless cup type SF LAY-OUT - TRAY III.

	Denomination	Qty	Order number
	Tray III. for application of cementless acetabular cup SF	1	301026
49	Acetabular reamer, diameter $arnothing$ 38 mm	1	304610
50	Acetabular reamer, diameter $arnothing$ 40 mm	1	304615
51	Acetabular reamer, diameter $arnothing$ 42 mm	1	304620
52	Acetabular reamer, diameter $arnothing$ 64 mm	1	304685
53	Acetabular reamer, diameter $arnothing$ 66 mm	1	304690
54	Acetabular cup template, diameter $arnothing$ 38 mm	1	304810
55	Acetabular cup template, diameter $arnothing$ 40 mm	1	304815
56	Acetabular cup template, diameter $arnothing$ 42 mm	1	304820
57	Acetabular cup template, diameter $arnothing$ 64 mm	1	304885
58	Acetabular cup template, diameter $arnothing$ 66 mm	1	304890
59	Trial head, diameter \varnothing 22 mm – M (POM-C) for implant	1	307198
60	Trial head, diameter $arnothing$ 22 mm – L (POM-C) for implant	1	307199
61	Hemisphere with "O" ring, diameter $arnothing$ 22 mm	1	304108
62	Hemisphere with "O" ring, diameter $arnothing$ 32 mm	1	304109
63	Handle hemispheres with "O" ring	1	304107
64	Trial head, diameter 32-S (POM-C) for implant	1	307210
65	Trial head, diameter 32-M (POM-C) for implant	1	307211
66	Trial head, diameter 32-L (POM-C) for implant	1	307212
67	Trial head, diameter 32-XL (POM-C) for implant	1	307213
68	Trial head, diameter 22 - M (POM-C) SF + cem	1	301288
69	Trial head, diameter 22 - L (POM-C) SF + cem	1	301289
70	Trial head, diameter 32-S (POM-C) SF + cem	1	301296
71	Trial head, diameter 32-M (POM-C) SF + cem	1	301297
72	Trial head, diameter 32-L (POM-C) SF + cem	1	301298

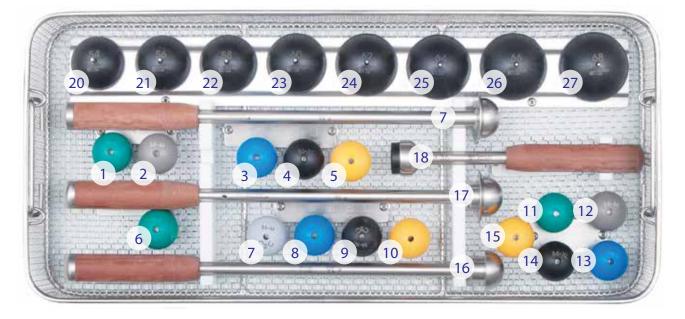


Instruments for application of cementless cup type SF LAY-OUT - TRAY III.			
	Denomination	Qty	Order number
73	Trial head, diameter 32-XL (POM-C) SF + cem	1	301299
74	Trial insert 40/22 - SF	1	304162
75	Trial insert 42/22 - SF	1	304163
76	Trial insert 44/22 - SF	1	304164
77	Trial insert 50/32 - SF	1	304170
78	Trial insert 52/32 - SF	1	304171
79	Trial insert 54/32 - SF	1	304172
80	Trial insert 56/32 - SF	1	304173
81	Trial insert 58/32 - SF	1	304174
82	Trial insert 60/32 - SF	1	304175
83	Trial insert 62/32 - SF	1	304176
84	Trial insert 64/32 - SF	1	304177
85	Trial insert 66/32 - SF	1	304178
86	Trial insert 68/32 - SF	1	304179

The cassette lay out has only an informative character and may be amended depending on inovation changes carried out.

Acetabular reamers and test templates with diameter 68 mm and 70 mm will be available separately.

The set of instruments - 301019



Instruments for application head total hip joint replacement, diameter 36 mm LAY-OUT - TRAY I.

	Denomination	Qty	Order number	* SF
	Tray I. for application head total hip joint replac., diamet.36 mm	1	301027	
1	Trial head 36 – S, cone 12/14, for rasp	1	307261	* SF
2	Trial head 36 – M, cone 12/14, for rasp	1	307262	* SF
3	Trial head 36 – L, cone 12/14, for rasp	1	307263	* SF
4	Trial head 36 – XL, cone 12/14, for rasp	1	307264	* SF
5	Trial head 36 – XXL, cone 12/14, for rasp	1	307265	* SF
6	Trial head 36 – S, cone 12/14, for rasp type CSC	1	307271	
7	Trial head 36 – M, cone 12/14, for rasp type CSC	1	307272	
8	Trial head 36 – L, cone 12/14, for rasp type CSC	1	307273	
9	Trial head 36 – XL, cone 12/14, for rasp type CSC	1	307274	
10	Trial head 36 – XXL, cone 12/14, for rasp type CSC	1	307275	
11	Trial head 36 – S, cone 12/14, for implant	1	307251	* SF
12	Trial head 36 – M, cone 12/14, for implant	1	307252	* SF
13	Trial head 36 – L, cone 12/14, for implant	1	307253	* SF
14	Trial head 36 – XL, cone 12/14, for implant	1	307254	* SF
15	Trial head 36 – XXL, cone 12/14, for implant	1	307255	* SF



Instruments for application head total hip joint replacement, diameter 36 mm LAY-OUT - TRAY I.			6 m m	
	Denomination	Qty	Order number	* SF
16	Head insertion instrument 36	1	301651	* SF
17	Cup insertion instrument without edge 36	1	302701	* SF
18	Cup insertion instrument with edge 36	1	302702	* SF
19	Offset cup insertion instrument with edge 36	1	302703	* SF
20	Trial insert 54/36 - SF	1	304181	* SF
21	Trial insert 56/36 - SF	1	304182	* SF
22	Trial insert 58/36 - SF	1	304183	* SF
23	Trial insert 60/36 - SF	1	304184	* SF
24	Trial insert 62/36 - SF	1	304185	* SF
25	Trial insert 64/36 - SF	1	304186	* SF
26	Trial insert 66/36 - SF	1	304187	* SF
27	Trial insert 68/36 - SF	1	304188	* SF

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The set of instruments - 300020



Tray - Trial head for ceramics LAY-OUT - TRAY I.

	Denomination	Qty	Order number	* SF
	Tray I. set of instruments for testing heads for ceramics	1	300021	
1	Trial head 28 - S, cone 12/14, for rasp type CSC - for ceramics	1	307240	
2	Trial head 28 - M, cone 12/14, for rasp type CSC - for ceramics	1	307241	
3	Trial head 28 - L, cone 12/14, for rasp type CSC - for ceramics	1	307242	
4	Trial head 32 - S, cone 12/14, for rasp type CSC - for ceramics	1	307245	
5	Trial head 32 - M, cone 12/14, for rasp type CSC - for ceramics	1	307246	
6	Trial head 32 - L, cone 12/14, for rasp type CSC - for ceramics	1	307247	
7	Trial head 28 - S, cone 12/14, for rasp type SF - for ceramics	1	307230	* SF
8	Trial head 28 - M, cone 12/14, for rasp type SF- for ceramics	1	307231	* SF
9	Trial head 28 - L, cone 12/14, for rasp type SF - for ceramics	1	307232	* SF
10	Trial head 32 - S, cone 12/14, for rasp type SF - for ceramics	1	307235	* SF
11	Trial head 32 - M, cone 12/14, for rasp type SF - for ceramics	1	307236	* SF
12	Trial head 32 - L, cone 12/14, for rasp type SF - for ceramics	1	307237	* SF
13	Trial head with "O" ring 28 - S, cone 12/14 for implant	1	307220	
14	Trial head with "O" ring 28 - M, cone 12/14 for implant	1	307221	
15	Trial head with "O" ring 28 - L, cone 12/14 for implant - for ceramics	1	307222	
16	Trial head with "O" ring 32 - S, cone 12/1 for implant - for ceramics	1	307225	
17	Trial head with "O" ring 32 - M, cone 12/14 for implant - for ceramics	1	307226	
18	Trial head with "O" ring 32 - L, cone 12/14 for implant - for ceramics	1	307227	

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Implants

Acetabular components - cups

Cup of total endoprostheses intended for implantation without bone cement is in complete assembly, consist of a shell and articulated insert. Shells with slotted holes can be fixed to the bottom of acetabulum special screws.

Cementless Shell – type SF

Cementless shell - type SF standard / B3

Material: Shell - Unalloyed titanium (ISO 5832-2)



Cementless shell - type SF flat



Cementless shell – type SF standard		
ØD [mm]	V [mm]	Order number
40	23	332328
42	24	332329
44	25	332330
46	26	332332
48	27	332334
50	28	332336
52	29	332338
54	30	332340
56	31	332342
58	32	332344
60	33	332346
62	34	332348
64	35	332350
66	36	332352
68	37	332354

Cementless shell – type SF flat		
ØD [mm]	V [mm]	Order number
48	22,5	332420
50	23,5	332422
52	24,5	332424
54	25,5	332426
56	26,5	332428
58	27,5	332430
60	28,5	332432

Shell of cementless cup – type SF/II/B 12 (a B 10)

Characteristics of the implant:

- Cup SF/II/B 12 is based on standard cup SF/II and is intended primarily for revision surgery. Cup is equipped with 12 slots for size 52-72 mm holes.
- Size 48-50 mm cups are equipped with a 10hole to ensure a sufficiently large area between the holes covered with a porous titaniumcoated for good contact with the bone to allow osteointegration.
- Holes are located on two concentric circles.
- Introduction of screws in the ceiling of acetabulum can be done from holes closer to the center cup, in distal part of the acetabulum are more often used holes closer to the edge of hole openings.
- This variability allows a hole to 6 tight-fitting bolts.
- Hole is intended mainly for revision operations, a loss and quality of bone tissue in acetabular implant will not allow use standard implant for higher risk of failure.
- Size of shells 70 and 72 mm are used insert size of 68 mm. These shells are therefore amplified by 2 mm and 4 mm.

Indication:

- weakening of the pillars
- osteoporosis
- defect in bottom of 2-3cm depending on the size of cup (possibly in combination with spongioplasty)



Cementless shell - type SF/II/B10

ØD [mm]	V [mm]	Order number
48	24	1.35.100
50	25	1.35.100

Cementless shell - type SF/II/B12

ØD [mm]	V [mm]	Order number
52	32	1.35.099
54	30	1.35.089
56	31	1.35.090
58	32	1.35.091
60	33	1.35.092
62	34	1.35.093
64	35	1.35.094
66	36	1.35.095
68	37	1.35.096

Cementless shell - type SF/II/B12 NON STANDARD

ØD [mm]	V [mm]	Order number
70	38	1.35.102
72	39	1.35.103



Cementless Shell – type SF

Surface of cementless shell - type SF

Material: Surface - Crosslinked ultra-high molecular weight polyethylene (ISO 5834-2)





Surface of cementless shell – type SF					
Shell diameter - D (as per above) [mm]	Ø A [mm]	Order number	Shell diameter - D (as per above) [mm]	Ø A [mm]	Order number
40		332498	50		332606
42	22	332499	52		332608
44		332500	54		332610
46		332502	56		332612
48		332504	58	32	332614
50		332506	60	52	332616
52		332508	62		332618
54		332510	64		332620
56		332512	66		332622
58	28	332514	68		332624
60		332516	54		332581
62		332518	56		332582
64		332520	58		332583
66		332522	60	26	332584
68		332524	62	36	332585
			64		332586
			66		332587
			68		332588

Catalogue

Cementless Shell – type SF

Surface of cementless shell - type SF with offset 10°

Material:Surface - Crosslinked ultra-high molecular weight polyethylene
(ISO 5834-2)





Surface of cementless shell – type SF with offset 10°					
Shell diameter - D (as per above) [mm]	Ø A [mm]	Order number	Shell diameter - D (as per above) [mm]	Ø A [mm]	Order number
40		332528	50		332636
42	22	332529	52		332638
44		332530	54		332640
46		332532	56		332642
48		332534	58	32	332644
50		332536	60	32	332646
52		332538	62		332648
54	28	332540	64		332650
56		332542	66		332652
58		332544	68		332654
60		332546	54		332591
62		332548	56		332592
64		332550	58		332593
66		332552	60	26	332594
68		332554	62	36	332595
			64		332596
			66		332597
			68		332598

Surface of cementless shell - type SF flat



Surface of cementless shell – type SF flat				
Shell diameter - D (as per above) [mm]	Ø A [mm]	Order number		
48		332564		
50		332566		
52		332568		
54	28	332570		
56		332572		
58		332574		
60		332576		

Cementless Shell – type SF

Cortical screw for cementless shell - type SF

Material: Fixation screws - Wrought titanium 6Al-4V alloy (ISO 5832-3)



Cortical crews for cementless shell – type SF				
Diameter [mm]	L [mm]	Order number		
	15	331906		
	20	331908		
	25	331910		
4 5	30	331912		
4,5	35	331914		
	40	331916		
	45	331918		
	55	331922		

Cancellous screw for cementless shell - type SF



Cancellous screw for cementless shell – type SF				
Diameter D [mm]	L [mm]	Order number		
	20	331948		
	25	331950		
	30	331952		
6,5	35	331954		
	40	331956		
	45	331958		
	55	331962		

Cancellous screw for cementless shell - type SF, L 20 mm

3,5				
Ĩ	L			
<i>P</i>				
D				

Cancellous screw L – 20 mm for cementless shell – type SF				
Diameter D [mm]	L [mm]	Order number		
6,5	20	331948		





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VALID SINCE: 8.4.2013

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