LINK®

i1 CUP™

Cementless Acetabular Cup System

Presented by:

CE 0426

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i1Cup™ Cementless Acetabular Cup System

System Description

The i1Cup™ Acetabular System represents an innovative solution for primary acetabular replacement, offering surgeons *a versatile combination of high range of motion bearings together with top performance coating technology to promote bone on-growth.*

i1Cup™ is a cementless hemispheric press-fit acetabular cup made of titanium alloy with equatorial grooves.

Best Bone Integration

To encourage osseointegration, the porous titanium surface coating produced with Vacuum Plasma Spray technique (TVPS) is available with electrochemically deposited CaP coating (calcium phosphate).

Primary Stability

The hemispheric cup features a polar flattening *to allow a secure and strong primary fixation at the equatorial ring.*

The system has a modular structure, offering numerous possible combinations with different inserts.

Inserts are available in standard UHMWPE, crosslinked UHMWPE with Vitamin E and latest generation ceramics.

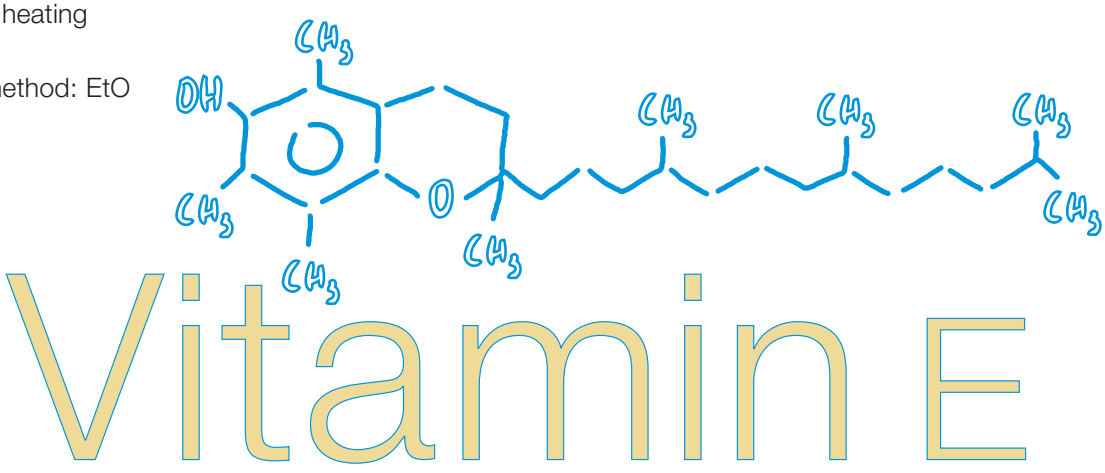
The i1Cup™ has 3 dome holes to house the stabilizing screws and one color coded peep hole. The holes are fitted with pre-assembled occluders.

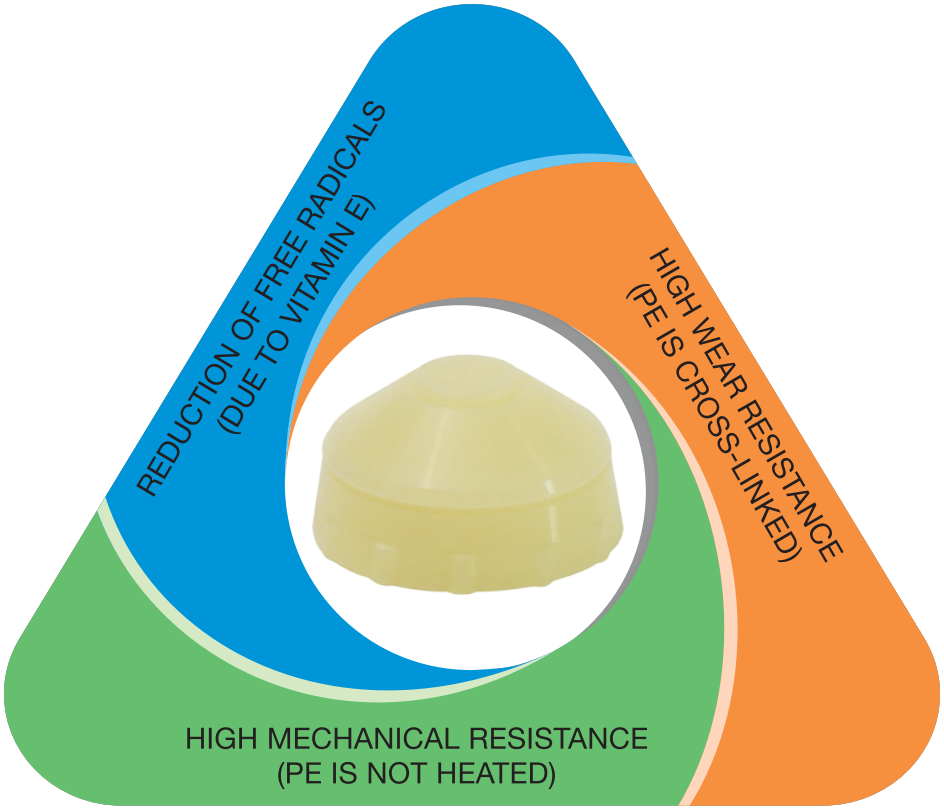
i1Cup™ Main Features:

- Press-fit fixation
- 14 sizes from 44 mm to 70 mm
- Titanium alloy with osteoconductive coating
- Equatorial grooves to improve primary stability
- Snap-lock mechanism for a safe locking of polyethylene inserts
- Conical coupling to avoid back side wear
- Inserts: standard UHMWPE, Vitamin E cross-linked UHMWPE or ceramic
- Optional screws to increase primary stability
- Available multi hole version

Cross-linked Polyethylene with Vitamin E - Main Features:

- UHMWPE blended with Vitamin E 0,1%
- Irradiation for cross-linking: 75 kGy
- No additional heating
- Sterilization method: EtO





Indications/Contraindications

Note: for specific indications/contraindications, see page 19.

Metal Casings

Material: Titanium alloy.
Double Coating (titanium Ti / calcium phosphate CaP)

Metal casings Item no.	Outer Ø mm	for inserts size
100-005/44	44	#B
100-005/46	46	#B
100-005/48	48	#B
100-005/50	50	#C
100-005/52	52	#C
100-005/54	54	#D
100-005/56	56	#D
100-005/58	58	#E
100-005/60	60	#E
100-005/62	62	#E
100-005/64	64	#E
100-005/66*	66	#E
100-005/68*	68	#E
100-005/70*	70	#E

*on request

Bone screws for metal casings
Material: Titanium alloy

Item no.	Ø Length mm
180-658/15	6.5 x 15
180-658/20	6.5 x 20
180-658/25	6.5 x 25
180-658/30	6.5 x 30
180-658/35	6.5 x 35
180-658/40	6.5 x 40

Metal casings i1Cup™-R

Material: Titanium alloy.
Double Coating (titanium Ti / calcium phosphate CaP)

Metal casings Item no.	Outer Ø mm	for inserts size
100-102/50	50	#C
100-102/52	52	#C
100-102/54	54	#D
100-102/56	56	#D
100-102/58	58	#E
100-102/60	60	#E
100-102/62	62	#E
100-102/64	64	#E
100-102/66	66	#E
100-102/68	68	#E
100-102/70	70	#E
100-102/72	72	#F
100-102/74	74	#F
100-102/76	76	#F
100-102/78	78	#F
100-102/80	80	#F

Cross-linked Polyethylene Inserts with Vitamin E

standard
Material: UHMWPE Cross-linked with Vitamin E

Item no.	Inner Ø mm	Insert size
100-008/28*	28	#B
100-008/32	32	#B
100-009/28*	28	#C
100-009/32*	32	#C
100-009/36	36	#C
100-010/28*	28	#D
100-010/32*	32	#D
100-010/36	36	#D
100-010/40*	40	#D
100-011/28*	28	#E
100-011/32*	32	#E
100-011/36	36	#E
100-011/40*	40	#E

*on request

standard - ONLY FOR I1CUP™-R
Material: UHMWPE Cross-linked with Vitamin E

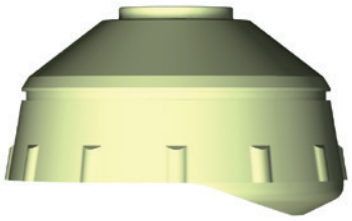
Item no.	Inner Ø mm	Insert size
100-016/28*	28	#F
100-016/32*	32	#F
100-016/36	36	#F
100-016/40*	40	#F

*on request

anti-luxation
Material: UHMWPE Cross-linked with Vitamin E

Item no.	Inner Ø mm	Insert size
100-012/28	28	#B
100-013/28*	28	#C
100-013/32	32	#C
100-014/28*	28	#D
100-014/32*	32	#D
100-014/36	36	#D
100-015/28*	28	#E
100-015/32*	32	#E
100-015/36	36	#E
100-015/40*	40	#E

*on request



anti-luxation - ONLY FOR I1CUP™-R
Material: UHMWPE Cross-linked with Vitamin E

Item no.	Inner Ø mm	Insert size
100-017/28*	28	#F
100-017/32*	32	#F
100-017/36	36	#F
100-017/40*	40	#F

*on request

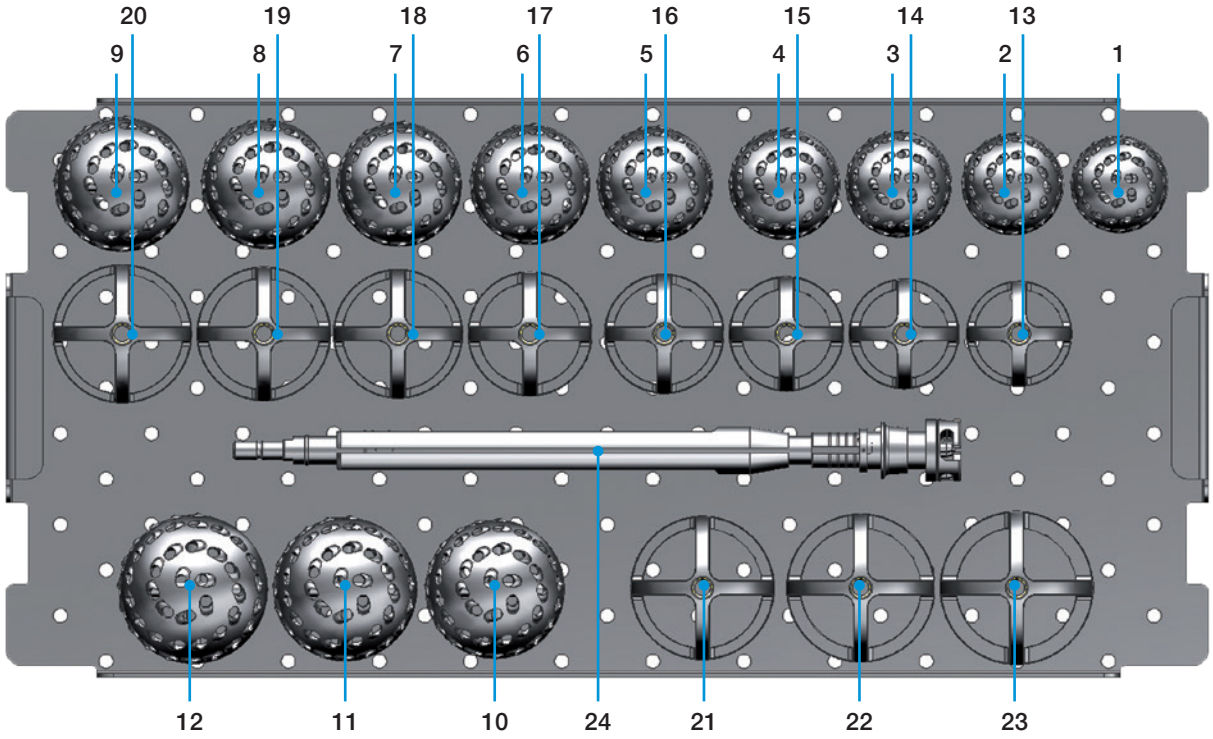
Ceramic Inserts

Ceramic inserts
Material: Cerasurf™ Alumina matrix composite

Item no.	Inner Ø mm	Insert size
100-018/32	32	#B
100-019/36	36	#C
100-020/36	36	#D
100-021/36	36	#E
100-022/36	40	#F

Instrument Set for i1Cup™ Cementless Acetabular Cup

Item no.	**i1Cup™ instrument set,** complete
100-900/00	**Container** with tray insert and lid, sterilizable, only

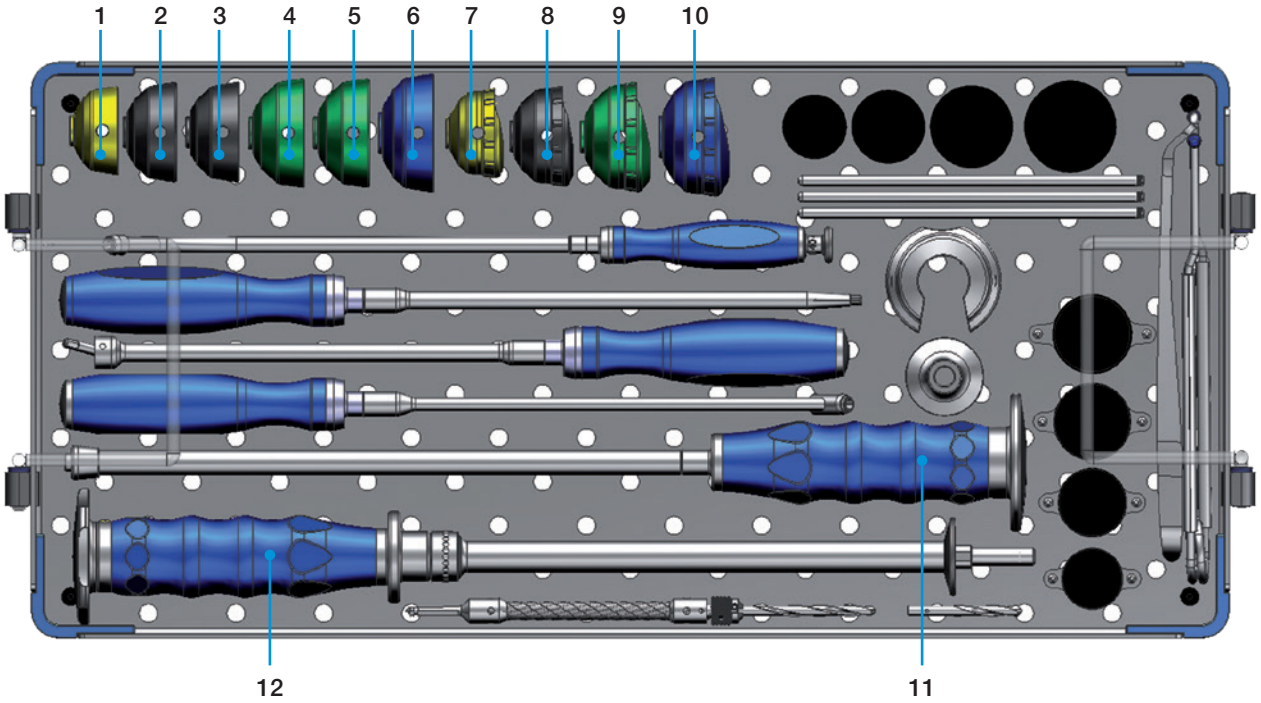


Acetabular reamer heads, interchangeable

	Item no	Ø mm	Qty.		Item no	Ø mm	Qty.
1	100-170/42	42	1	9	100-170/58	58	1
2	100-170/44	44	1	10	100-170/60	60	1
3	100-170/46	46	1	11	100-170/62	62	1
4	100-170/48	48	1	12	100-170/64	64	1
5	100-170/50	50	1				
6	100-170/52	52	1				
7	100-170/54	54	1				
8	100-170/56	56	1				

Trial Acetabular Cups

	Item no	Ø mm	Qty.		Item no	Ø mm	Qty.
13	100-160/44	44	1	20	100-160/58	58	1
14	100-160/46	46	1	21	100-160/60	60	1
15	100-160/48	48	1	22	100-160/62	62	1
16	100-160/50	50	1	23	100-160/64	64	1
17	100-160/52	52	1				
18	100-160/54	54	1				
19	100-160/56	56	1				
24	100-170/01	**Shaft with handle for acetabular reamer,** 312 mm, ZIMMER/JACOBS					



Trial Inserts Standard

	Item no	Ø mm	Size	Qty.
	100-130/28*	28	B	1
1	100-130/32	32	B	1
	100-131/28*	28	C	1
2	100-131/32	32	C	1
3	100-131/36	36	C	1
	100-132/28*	28	D	1
4	100-132/32	32	D	1

	Item no	Ø mm	Size	Qty.
5	100-132/36	36	D	1
	100-132/40*	40	D	1
	100-133/28*	28	E	1
	100-133/32*	32	E	1
6	100-133/36	36	E	1
	100-133/40*	40	E	1

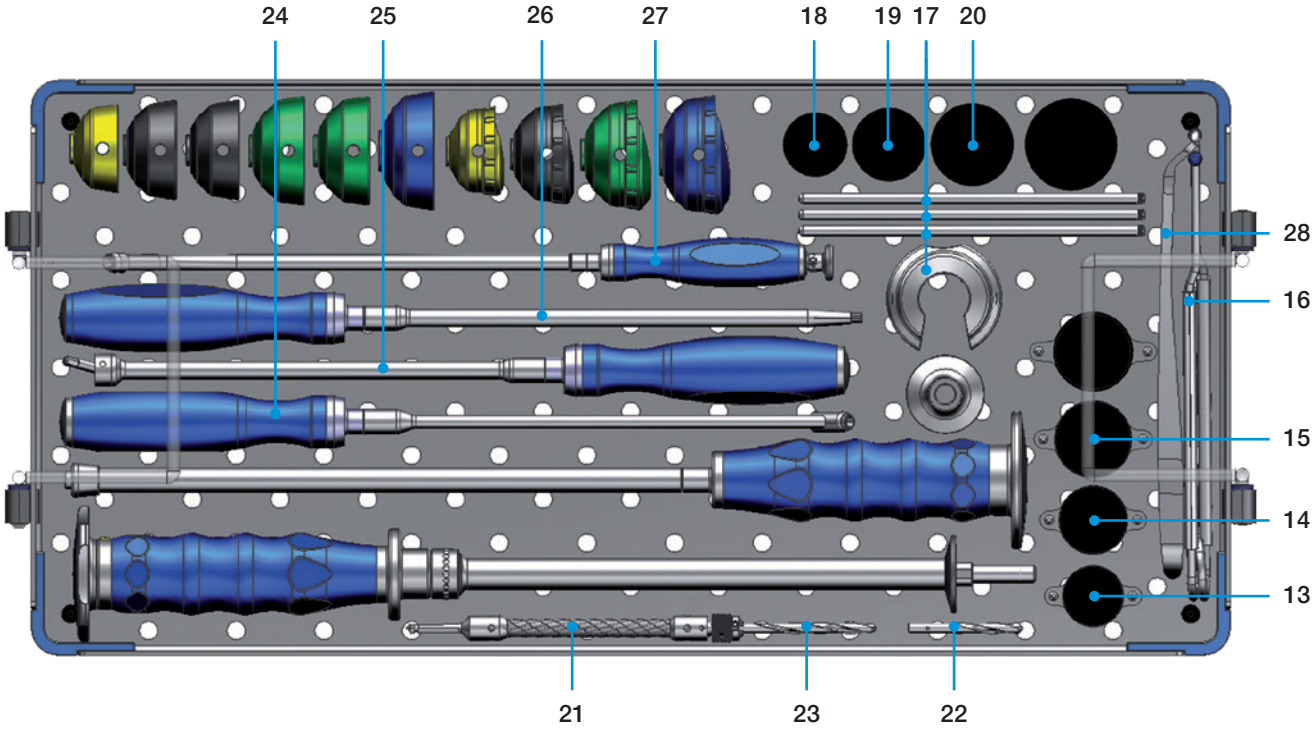
Trial Inserts anti-luxation

	Item no	Ø mm	Size	Qty.
7	100-140/28	28	B	1
	100-140/32*	32	B	1
	100-141/28*	28	C	1
8	100-141/32	32	C	1
	100-141/36*	36	C	1
	100-142/28*	28	D	1
	100-142/32*	32	D	1

	Item no	Ø mm	Size	Qty.
9	100-142/36	36	D	1
	100-142/40*	40	D	1
	100-143/28*	28	E	1
	100-143/32*	32	E	1
10	100-143/36	36	E	1
	100-143/40*	40	E	1

11	100-150/01	Easy straight cup impactor
12	100-150/04	Straight cup impactor

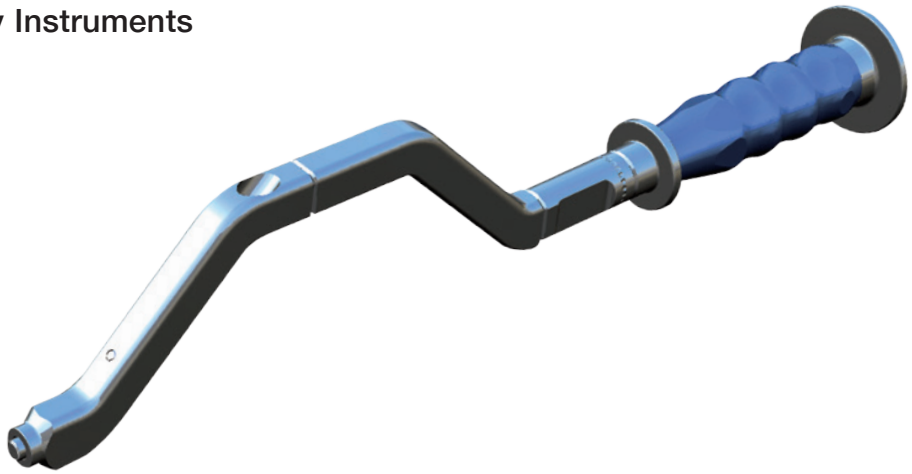
*on request



13	100-152/01	Impactor liner inlay 28
14	100-152/02	Impactor liner inlay 32
15	100-152/03	Impactor liner inlay 36
	100-152/04*	Impactor liner inlay 40
16	100-153/00	Liners removal spring
17	100-154/00	Aligner for impactor cup handle
18	100-155/01	Liner impactor 28
19	100-155/02	Liner impactor 32
20	100-155/03	Liner impactor 36
	100-155/04*	Liner impactor 40
21	100-608/01	Flexible drill handle
22	100-608/02	Short drill
23	100-608/03	Long drill
24	100-608/04	Drill driver handle
25	100-609/01	Flexible hexagonal screwdriver
26	100-609/02	Fixed hexagonal screwdriver
27	100-610/01	Holes depth gauge
28	100-611/01	Screws clamp

*on request

Complementary Instruments



	100-150/03	**Curved cup impactor**

Acetabular reamer heads, interchangeable

	Item no	Ø mm	Qty.		Item no	Ø mm	Qty.
1	100-170/66	66	1		100-170/74*	74	1
	100-170/68	68	1		100-170/76*	76	1
	100-170/70	70	1		100-170/78*	78	1
	100-170/72*	72	1		100-170/80*	80	1

Trial Acetabular Cups

	Item no	Ø mm	Qty.		Item no	Ø mm	Qty.
1	100-160/66	66	1		100-160/74*	74	1
	100-160/68	68	1		100-160/76*	76	1
	100-160/70	70	1		100-160/78*	78	1
	100-160/72*	72	1		100-160/80*	80	1

Trial Inserts Standard

	Item no	Ø mm	Size	Qty.
X	100-134/36	36	F	1

Trial Inserts anti-luxation

	Item no	Ø mm	Size	Qty.
X	100-144/36	36	F	1

i1Cup™-R instrument set, complete

	100- /	**Container** with tray insert and lid, sterilizable, only

*only for use with i1Cup-R

Preoperative Planning

To ensure the best possible treatment results, the appropriate implant should be selected during preoperative planning.
i1Cup™ X-ray templates are available in standard 1,10:1.
Together with an up-to-date plain X-ray of the pelvis, the X-ray templates are a practical aid to enable determination of the surgical intervention and of the correct implant size.

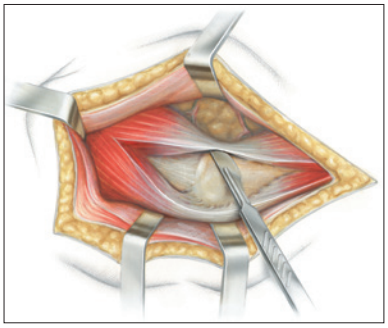
The aim of preoperative planning is to establish the approximate size of the implant required and the optimal position in which to place it. Surgical complications should be avoided by means of careful planning.

In principle, a load-bearing, stable acetabular fossa and solid lateral osseous coverage is desirable.
To achieve a press-fit with primary stability, the osseous circumference of the acetabulum must be well preserved.
The inclination of the shell should not be significantly above or below 45°.
The anteversion should not be significantly above or below 15°.
Placement outside of these boundaries will result in reduced range of motion and could subsequently lead to subluxation and/or dislocation of the joint.

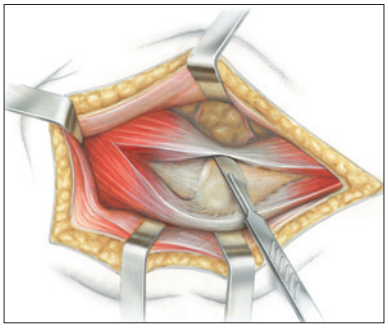
Surgical Approaches

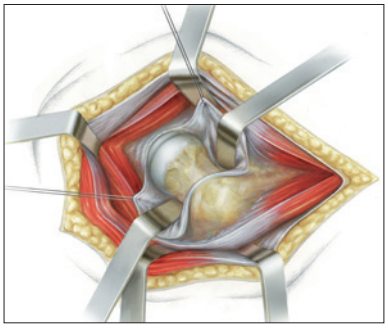
The choice depends on the surgeon‘s experience and his/her decision based on the individual situation.

The following approaches are common:
- antero-lateral **- Watson Jones (A)**
- direct lateral **- Hardinge (B)**
- postero-lateral **- Moore (C)**

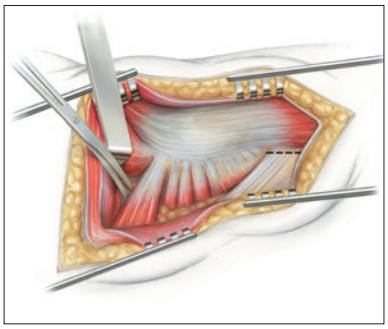


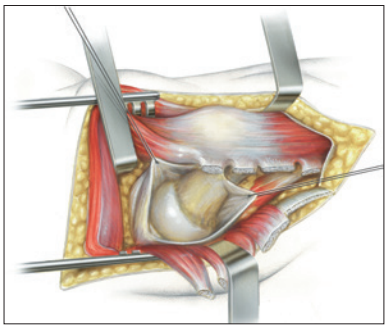
A: Watson Jones



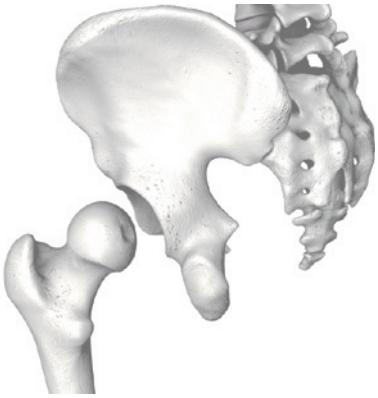


B: Hardinge





C: Moore



Dislocation of the Hip Joint

After dislocation of the femoral head, the femoral neck and the proximal rim of both trochanters are exposed and existing osteophytes of the femoral head removed.

Femoral Head Resection

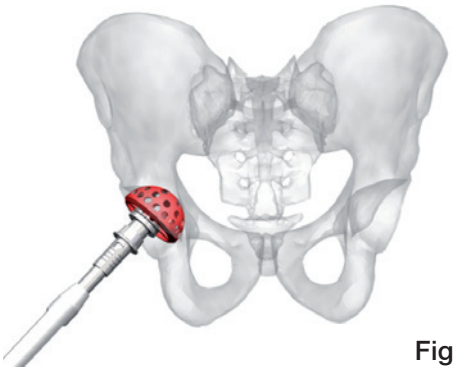


Fig. 1

Preparation and Reaming of the Acetabulum

Depending on the approach used, the leg is rotated so that the acetabulum is well exposed.
The initial reamer size corresponds to the width of the acetabular cup entrance (Fig. 1).
Then reamers with increasing diameters are applied until areas of bloody subchondral compacta become visible but without compromising the supportive structure for secure anchoring of the metal casing.
It is essential to keep the reamer head absolutely steady.

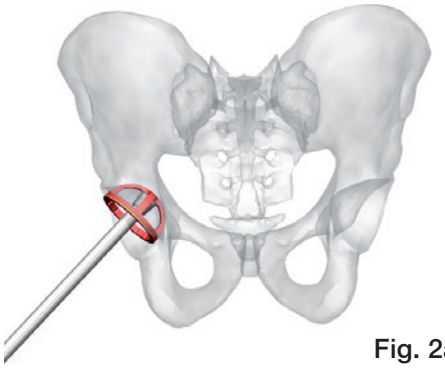


Fig. 2a

Cup Trial and Liner Trial

The cup trial (Fig. 2a and 2b) is used to determine the size of metal casing required as the reamed cavity may be larger than was originally intended.
As soon as the cup trial is firmly seated in the reamed acetabulum the corresponding size of the metal casing is to be selected.
The trial liner can be inserted inside the cup trial (Fig. 3). The trial liner can be fixed by screwing the internal screw, directly connected to it (Fig. 4).

Fig. 2b

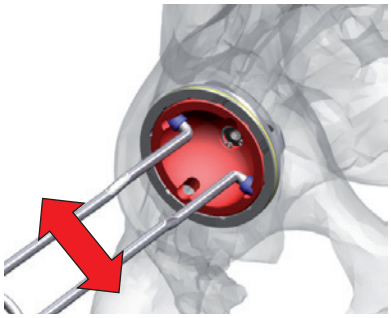


Fig. 3

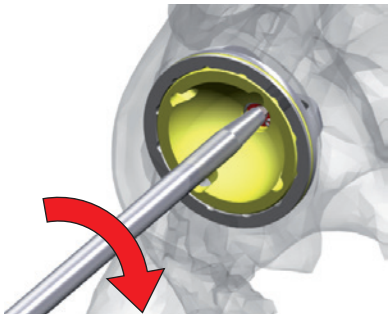


Fig. 4

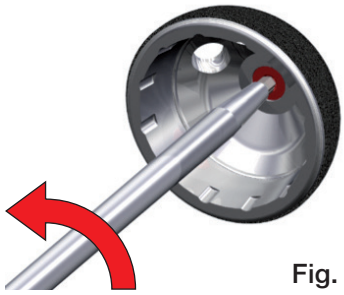


Fig. 5

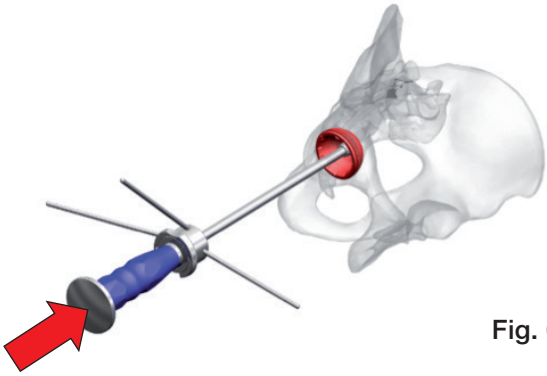


Fig. 6

Implantation of Metal Casing

Remove the polar plug inside the cup (Fig. 5).
The polar plug is colour coded refering to the liners coupling.
Connect the metal casing to the impactor.
Attach the alignment guide to the cup impactor in such way that the alignment guide aligns exactly to the small pin on the metal casing (Fig. 6).
According to the patient‘s side to be treated, connect the alignment rod to the alignment guide using the corresponding receptacle (left or right).
The metal casing is then driven into the prepared acetabulum. The rim of the casing should be parallel to the acetabular entrance plane for secure seating in the surrounding bone.

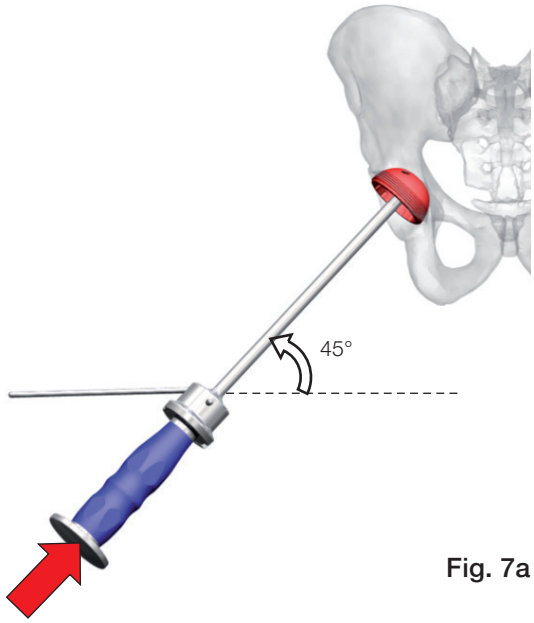


Fig. 7a

Positioning of the Metal Casing

The metal casing is aligned for 45° inclination using the corresponding alignment guide which must be attached to the impactor handle.
To achieve 10° anteversion the alignment rod must be aligned in parallel to the patient‘s body.

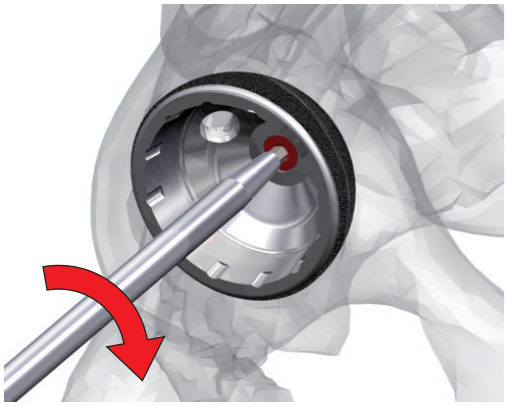


Fig. 8

Impaction and Closure of the Peep-Hole Locking Screw

After impaction the central hole is closed with the peep-hole locking screw.
If addistional bone screws are used the locking screws must first be removed from inside the cup.

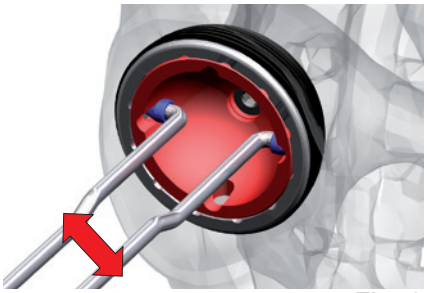


Fig. 9

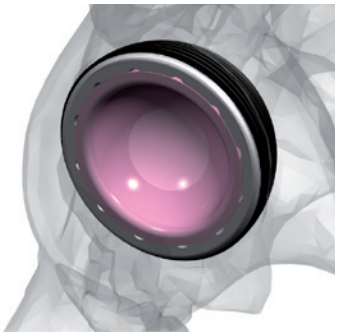


Fig. 10

Fig. 11

Fig. 11a

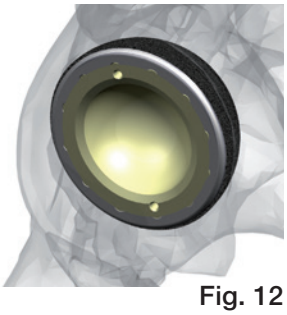


Fig. 12

Trial Reduction

The plastic trial insert is placed in the metal casing. Refer to colour code for right coupling.
The trial reduction indicates the correct positioning of the trial insert and the head-neck length.

Implantation of Final Liners

Polyethilene liners and ceramic liners can be used into i1Cup™ system. Polyethilene liners are available in standard and anti-luxation versions.

Ceramic liners

Before placing the insert, clean the inside of the augment carefully and check that surrounding soft tissue does not hinder hinder the procedure.
Carefully place the ceramic liner inside the cup.
Check that the insert is correctly seated by feeling round the entire edge. The edge of the insert must not protrude over the edge of the metal casing.
The insert can otherwise become damaged.
If the insert jams in the oblique position, it must be removed, which can be carried out by lightly hitting the edge of the metal casing using the handle of a suitable instrument. The vibration causes the insert to spring out. If the ceramic liner is correctly placed inside the cup, slightly impact it.

Polyethilene liners

Before placing the insert, clean the inside of the augment carefully and check that surrounding soft tissue does not hinder hinder the procedure.
Select the right impactor tips, according to the colour code of the final liner. Screw it on the impactor.
Couple the two small holes of the liner with the two small pins (Fig. 11, 11a and 12).

Place the polyethilene liner inside the cup:

- inserti the liner into the cavity, till the first contact with the metal shell
- find the right position by rotating the liner, there must be correspondance between liner's pegs and cup's holes
- finally impact the liner

X-ray Templates

Item no.	**X-ray templates** for i1Cup™
100-900/10	**Metal casings** 110% actual size, 1 set of 2 sheets

Item no.	**X-ray templates** for i1Cup™
100-900/15	**Metal casings** 115% actual size, 1 set of 2 sheets

Instructions for Cleaning and Maintenance

Specific instructions for instruments are available on request from info@linkitaliaspa.it

Literature

Articles

Design Dossier LINK Italia (intern)
Ullmark G, Sorensen J, Nilsson O. Analysis of bone formation on porous and calcium phosphate-coated acetabular cups: a randomised clinical (18F)fl uoride PET study. Hip international: the journal of clinical and experimental research on hip pathology and therapy. 2012;22(2):172-8.

UHMWPE for Arthroplasty
Polietilene per artroprotesi
L. Costa - E.M. Brachdel Prever
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Indications/Contraindications

	i1Cup™ Acetabular Cup System	i1Cup™ Multi Hole Shell
General Indications		
Mobility-limiting diseases, fractures or defects which cannot be treated by conservative or osteosynthetic procedures	X	X
Indications		
Primary and secundary coxarthrosis	X	X
Osteoarthritis	X	X
Necrosis of the femoral head	X	X
Femoral neck fractures	X	X
Revision after implant loosening	X*	X*
Contraindications		
Poor general state of health	X	X
Acute and chronic infections, local and systemic	X	X
Allergies due to (implant) materials	X	X
Distintive muscular-, nerve-, vascular or other diseases which put the affected limb at risk	X	X
Insufficient/inadequate bone mass which prevents a stable anchor of the prosthesis	X	X
Acetabulum fracture	X	X
Relative Contraindications		
Adiposity	X	X
Lacking or foreseeable not assured compliance	X	X
Foreseeable overload/overstressing of the joint prosthesis	X	X
Osteoporosis	X	X
Acetabular defects	X	X

*Dependent on bone density

Please note: These indications/contraindications refer to standard cases. The ultimate decision on whether or not an implante is suitable for a patient must be made by the surgeon based on his/her individual analysis and his/her experience.

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*on request

Important Information

Please note the following regarding the use of our implants:

1. **Choosing the right implant is very important.**
   The size and shape of the human bone determine the size and shape of the implant and also limit the load capacity. Implants are not designed to withstand unlimited physical stress. Demands should not exceed normal functional loads.

2. **Correct handling of the implant is very important.**
   Under no circumstances should the shape of a finished implant be altered, as this shortens its life span.
   Our implants must not be combined with implants from other manufacturers.

   The instruments indicated in the Surgical Technique must be used to ensure safe implantation of the components.

3. **Implants must not be reused.**
   Implants are supplied sterile and are intended for single use only. Used implants must not be reused.

4. **After-treatment is also very important.**
   The patient must be informed of the limitations of the implant. The load capacity of an implant cannot compare with that of healthy bone!

5. **Unless otherwise indicated, implants are supplied in sterile packaging.**
   Note the following conditions for storage of packaged implants:

- Avoid extreme or sudden changes in temperature.
- Sterile implants in their original, intact protective packaging may be stored in permanent buildings up until the “Use by” date indicated on the packaging.
- They must not be exposed to frost, dampness or direct sunlight, or mechanical damage.
- Implants may be stored in their original packaging for up to 5 years after the date of manufacture. The “Use by” date is indicated on the product label.
- Do not use an implant if the packaging is damaged.

6. **Traceability is important.**
   Please use the documentation stickers provided to ensure traceability.

7. **Further information** on the material composition is available on request from the manufacturer.

Follow the instructions for use!

Link Italia SpA, Milano

The Surgical Technique described has been written to the best of our knowledge and belief, but it does not relieve the surgeon of his/her responsibility to duly consider the particularities of each individual case.

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