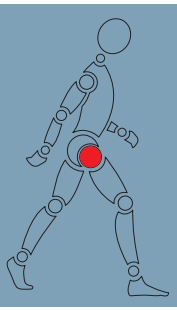
OVER 30 YEARS OF EXPERIENCE IN MEDICAL TECHNOLOGY

30 YEARS

BSC Cup
Surgical Technique



swiss design
swiss made
swiss quality

stemcup

Medical products in motion

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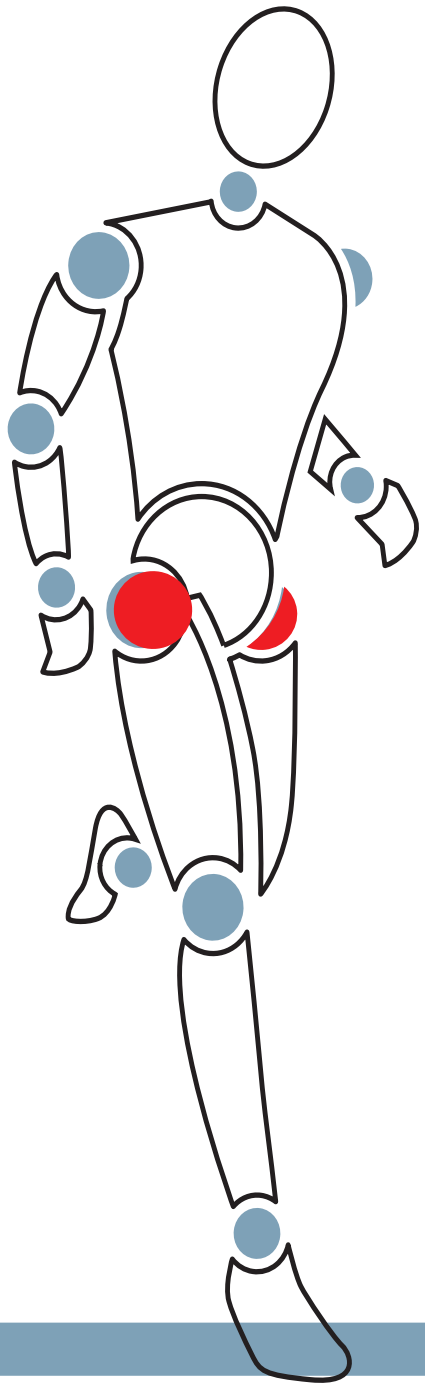
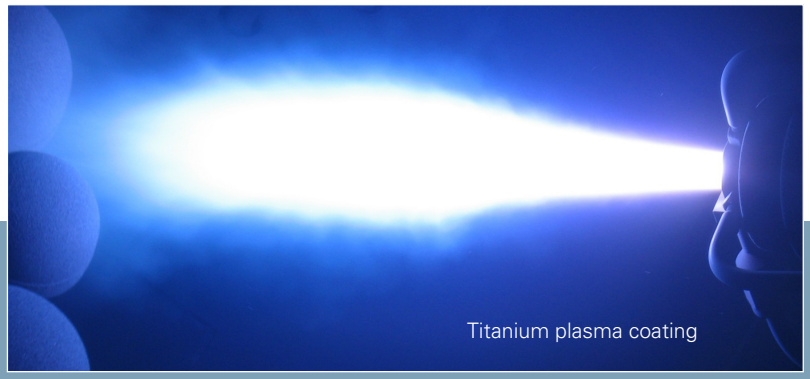


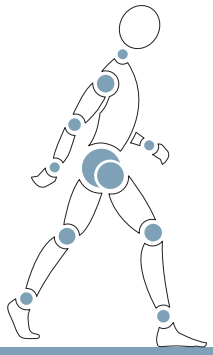
1. Introduction


Titanium plasma coating

The spherical BSC Hip Cup developed in collaboration with Prof. Dr. med. G. Biehl, has the purpose to achieve the optimal restoration of the anatomical cup function of the hip joint under physiological load. The press-fit cup is slightly flattened at the pole and is larger in diameter than the pre-reamed acetabular bed in the bone. 11 diameter sizes from 46 to 66 mm allow an optimal adaptation to the anatomical conditions. A good secondary stability is achieved through a rough surface coating of pure titanium with a roughness value of Ra 30-35 µm so that a good osseointegration is ensured. In addition, bone screws may be used.
Additional the BSC Cup is available with a hydroxylapatite-coating to enhance the osseointegrative ability. The HA coated cup is closed with cover screws.

Polyethylene, Xonit X-PE, Xonit-E X-PE and ceramic inlays are available. 4 inlays sizes cover all 11 cup sizes. The polyethylene inlays are also available in a 10° dysplasia version with an anti-dislocation shoulder.

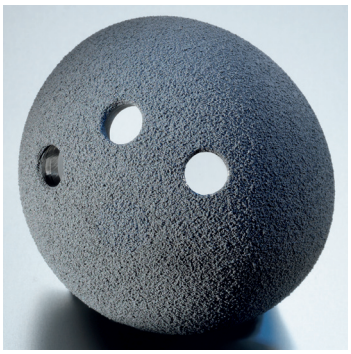
It's possible to use ballheads with 36mm diameter from cup size 50 with ceramic and Xonit X-PE-Inlays. From cup size 54 it's possible to use 40 ballheads. This leads to significantly more ROM, greater dislocation paths and less impingement against smaller ball heads and brings the patient felt more freedom of movement.



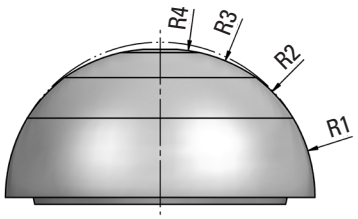
2. System description

2.1. Prosthesis design

- 11 cup sizes of Ø 46 - 66 mm
- closed type and 3 hole type
- material: pure titanium / ISO 5832-2
- titanium plasma coating
  roughness R_a 30-35 µm additionally with HA coating available
- cup Ø = reamer Ø + oversize (oversize increasing with the cup size)
- flattened cup pole
- no instrument access on the tapers contact surface, thus avoiding damage to the Cermamic-Inlay



cementless BSC Cup



BSC press-fit cup with different radiuses

2.2. Cup inlays

	Ø28	Ø32	Ø36	Ø40
PE-Inlay standard	size 46-66	size 50-66	———	———
PE-Inlay dysplasia	size 46-66	size 50-66	———	———
Xonit X-PE Inlay standard	size 46-66	size 46-66	size 50-66	size 54-66
Xonit X-PE Inlay dysplasia	size 46-66	size 50-66	size 54-66	———
Xonit-E X-PE Inlay standard	size 46-66	size 46-66	size 50-66	size 54-66
Xonit-E X-PE Inlay dysplasia	size 46-66	size 50-66	size 54-66	———
Ceramic-Inlay	size 46-66	size 46-66	size 50-66	size 54-66

PE-Inlay standard

Xonit / Xonit-E X-PE Inlay

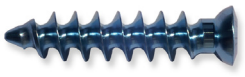
Ceramic-Inlay

2. System description

2.3. Bone screws

Material: Ti6Al4V / ISO 5832-3

300.65.20	Cancellous bone screw 6,5x20 mm
300.65.25	Cancellous bone screw 6,5x25 mm
300.65.30	Cancellous bone screw 6,5x30 mm
300.65.35	Cancellous bone screw 6,5x35 mm
300.65.40	Cancellous bone screw 6,5x40 mm
300.65.20-S	Cancellous bone screw 6,5x20 mm (sterile)
300.65.25-S	Cancellous bone screw 6,5x25 mm (sterile)
300.65.30-S	Cancellous bone screw 6,5x30 mm (sterile)
300.65.35-S	Cancellous bone screw 6,5x35 mm (sterile)
300.65.40-S	Cancellous bone screw 6,5x40 mm (sterile)
300.67.20	Corticalis screw 4,5x20 mm
300.67.30	Corticalis screw 4,5x30 mm
300.67.40	Corticalis screw 4,5x40 mm



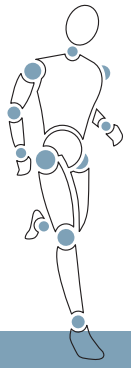
Cancellous bone screws

STERILE R

Corticalis screws

2.4. Instrumentation

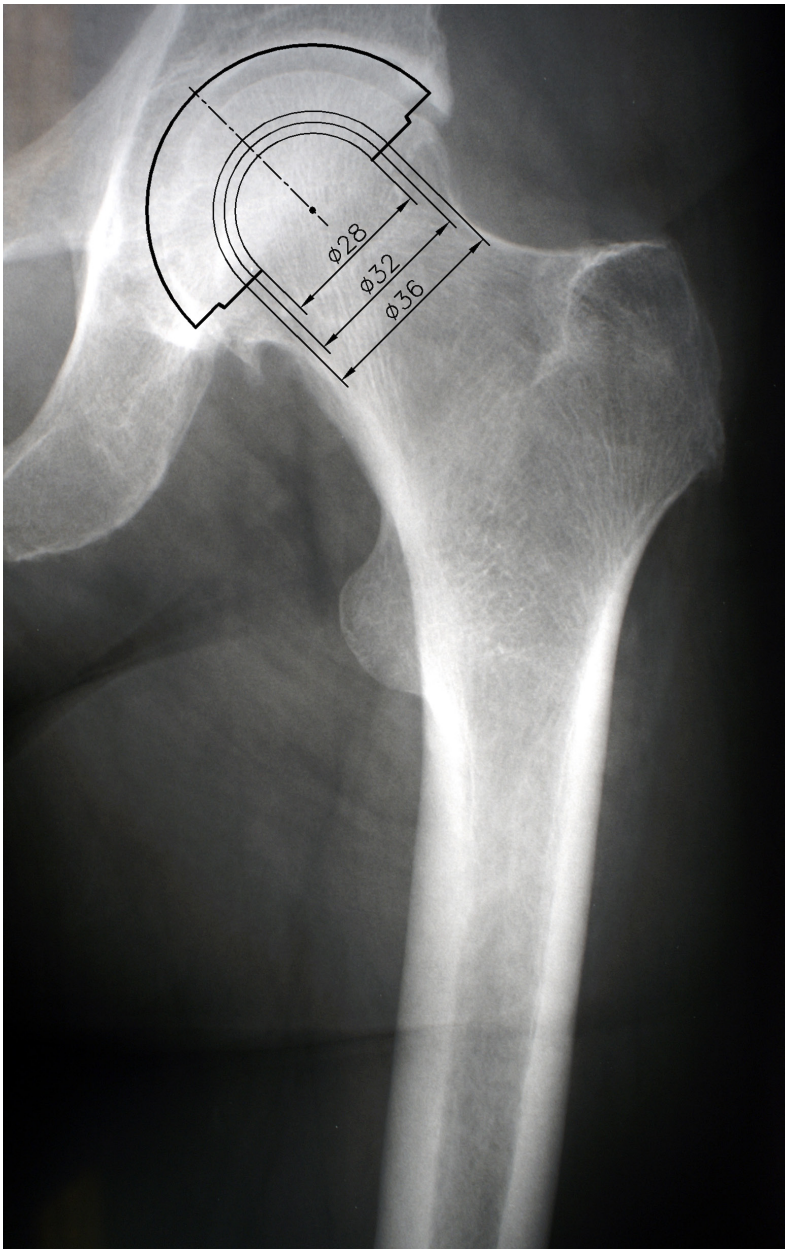
Simple and functional instrumentation supports a constantly controllable and safe preparation and insertion of the implant.

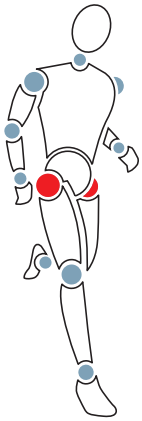


3. Preoperative planning

Using the available X-ray templates, it is possible to plan the cup size and the cup position.

The X-ray films are also available in digital formats.





4. Indications / Contraindications / E-IFU

A prosthesis should be considered only after all other surgical methods of treatment and/or conservative measures have been carefully weighed against each other and none has been judged to be more appropriate.
Even a most successfully implanted artificial joint is inferior to a normal, sound joint. On the other hand, an artificial joint can be a highly beneficial substitute for a severely deformed and diseased joint, and is consequently a blessing for the suffering patient, because it eliminates pain and is conducive to the restoration of good mobility and weight-bearing capacity.
Every artificial joint is subject to wear, which still remains a major problem awaiting solution. An initially stable prosthesis may become loose in the course of time. Wear and loosening are two major causes that may render revision surgery necessary.

4.1 Indications

It follows, from the above statements, that a prosthesis is indicated in cases where some of the following five basic conditions are fulfilled:

- noninflammatory degenerative joint disease (NIDJD) for example: osteoarthritis (arthrosis primary-, secondary- ,dysplasia-coxarthrose)
- inflammatory joint disease (IJD) for example: rheumathoide arthritis, post-traumatic arthritis condition resulting from previous surgery, e.g. osteosynthesis, joint reconstruction, arthrodesis, hemiarthroplasty or total hip replacement
- fracture or avascular necrosis of the femoral head

The surgeon should inform the patient of the risks associated with the implantation of a prosthesis, and the patient must consent to the operation, and – if necessary – sign the relevant declaration.

The following circumstances require special attention, as the can cause premature failure of the implants, like stem fractures, loosing, or increased abrasions.

- patient's overweight
- extreme loading expected as a result of work and sport
- epilepsy or other factors favouring repeated accidents with increased risk of fracture
- osteoporosis or osteomalacia
- past history and ongoing risk of infectious diseases with potential arthropathic manifestations
- severe deformation of the affected joint, which may render fixation of the implant more difficult
- weakening of the supporting structures due to tumours
- alcoholism or other addictions
- the taking of highly dosed cortisone or cytostatic drugs
- patient's mental inability to understand and follow the attending surgeon's instructions
- patients whose skeletons are not completely formed or are still growing. A risk/benefit analysis is the responsibility of the treating physician. Note however that STEMCUP does not accept any liability in any case for such uses.

4. Indications / Contraindications / E-IFU

4.2 Contraindicatons

The following conditions are generally accepted as contraindications to the implantation of a joint prosthesis:

- acute or chronic infection (local or systemic)
- severe muscular, neurological or vascular disease threatening the extremity concerned
- loss of bone structure or poor quality of bone, precluding proper anchorage of the implant
- any concomitant disease which may compromise the function of the implant
- possible patient allergy to the material(s) used in the implant or prosthesis

Delta Inlay advanced contraindications

The joint may not luxate during movement or sublucate through impingement of the implant components or of soft tissue. The inclination of the cup components should not significantly exceed or fall below a value of 40-45°. The anteversion of the cup components should not significantly exceed or fall blow a value of 10-20°. Outside this range there are restrictions in movement which can lead to subluxations and/or dislocatons of the femoral head from the BIOLOX®delta Inlay.

For a cup position which lies outside the above-mentioned values, a BIOLOX®delta Inlay must not be used. For acetabular shells in retroversion, a BIOLOX®delta Inlay must not be used. Possible consequences are an increase in the surface pressure on the cup edge with grain break-out from the BIOLOX®delta Inlay associate with increased ceramich debris. Excessive cermic debris can lead to adverse tissue reactions, lossening of the prosthesis and in extreme cases ceramic breakage. Ensure adequate joint tension is achieved on implantation, as luxation can also lead to the adverse results listed above.

4.3 E-IFU

The E-IFU (Instruction for Use) is available online.
On the product labels there will be the link to www.stemcup.com. On this website the electronic IFU can be downloaded. You need to enter the IFU Code which is printed on the product label to be forwarded to the page where you can download the appropriate IFU. In addition there is a QR code (2D barcode) on each label, which can be scanned by a smartphone and a QR code reader. If you scan this QR Code you'll be directly forwarded to the page with the appropriate IFU.

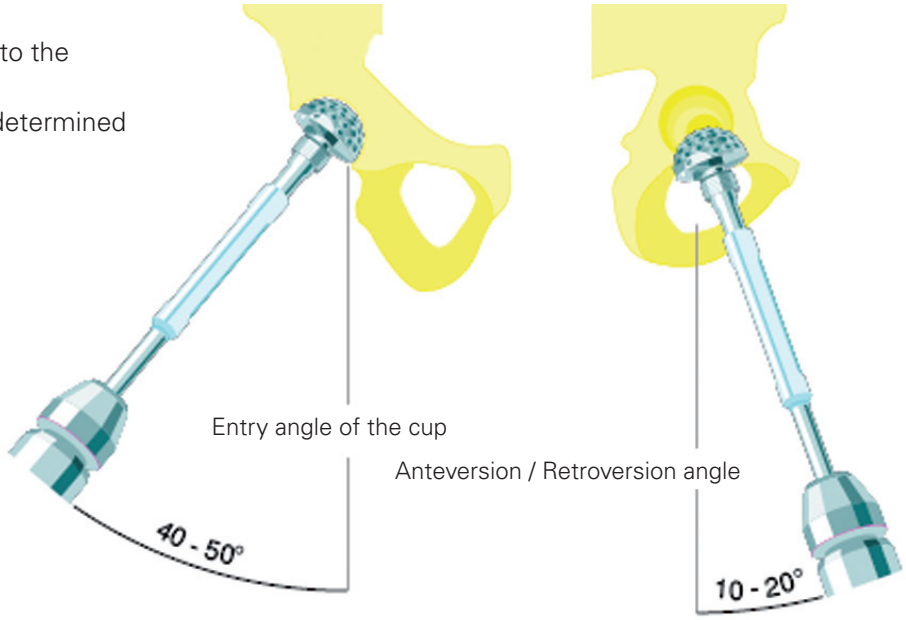
Before a user first uses a specific medical device of Stemcup a printed version of the specific IFU is provided. In the event of a revision of the IFU every customer will receive it in a printed version.

A printed version of the IFU can by requested at any time. Delivery of a printed version takes 1 to 7 days. Please send your IFU order by email to administration@stemcup.ch or send us a fax on the appropriate fax numbers of Stemcup Switzerland, Germany or Austria.

5. Surgical technique

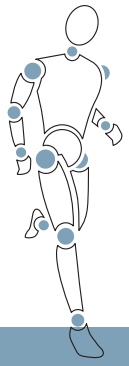
5.1 Guide shaft & Reamer

Ream the acetabulum stepwise to the suitable cup size.
The depth of the acetabulum is determined using the smallest reamer.



5.2 Impactor handle for trial cup

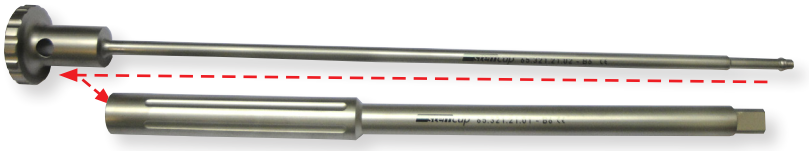
Drive in the trial cup using the handle (straight or curved version) to check the cup size and to make sure that the cup is positioned firmly.



5. Surgical technique

5.3 Cup inserter

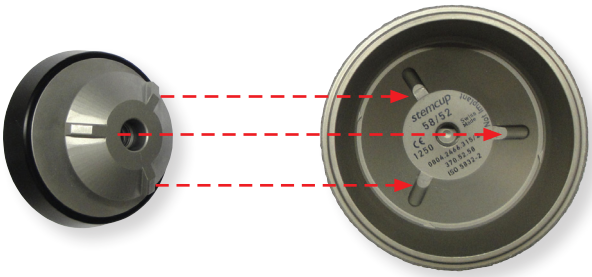
1. Insert the threaded rod into the setting device.



2. Insert the setting device into the setting device attachment.
   Now screw in the threaded rod into the setting device attachment.

3. The 120 degree shifted notches on the setting device, must be set into the slots on the bottom of the cup.
   Now, screw in the threaded rod into the cup.

Information!
The easiest way to screw in the threaded rod into the cup is, when the cup lays on the operating table.

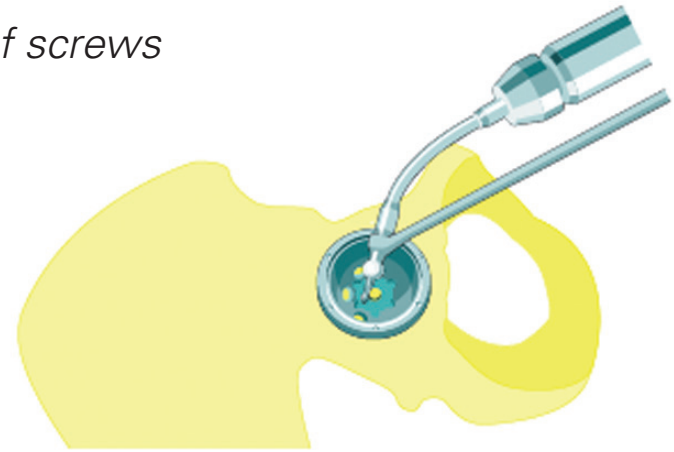


4. Now the setting device with the cup is ready for the operation and the cup can be impacted into the prepared acetabulum.

5. Surgical technique

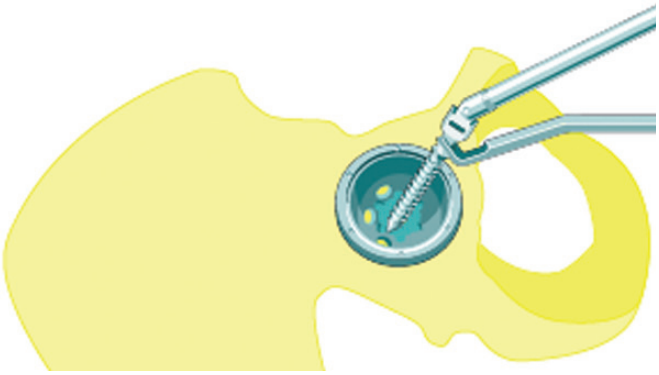
5.4 In case of additional use of screws

Pre-drill the screw holes using the drilling gauge and flexible drill bits (gives larger displacement for the drilling gauge and thus for the screw direction).



5.5 Screws

Fix the screw with a screw holder and screw it in with a cardan screwdriver. Screw holes which are not used, can be closed with cover screws.

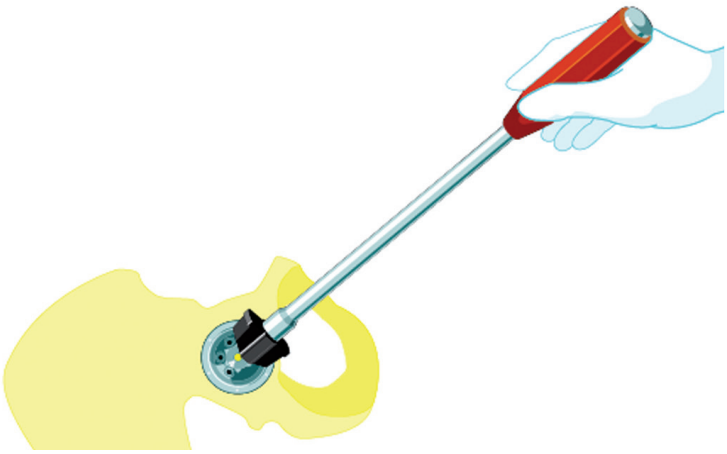


Attention!
Screws should not penetrate in soft tissue.
This may lead to complications.

5. Surgical technique

5.6 Master gauge

Screw a suitable master gauge onto the handle and by rotating it, check the tightness (possibility that the screws are inserted not deep enough).



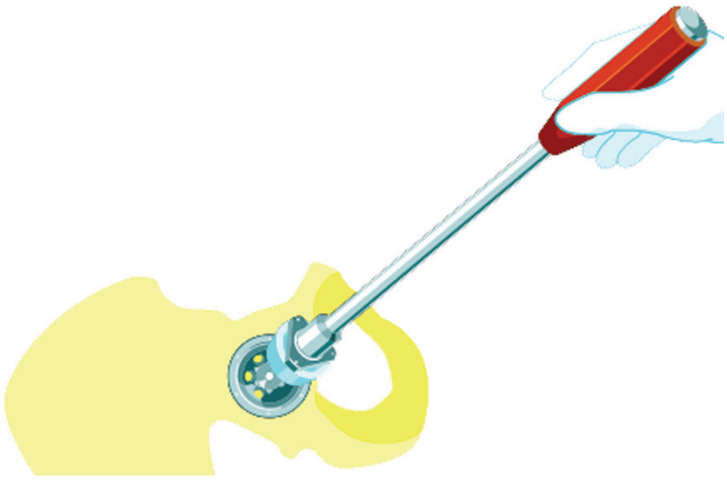
5.7 Insertion of PE-Inlay

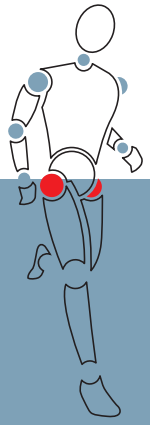
1. Select the desired PE-Inlay (standard or dysplasia 28 mm or 32 mm).

2. Fix the PE-Inlay on the appropriate PE inserter.

3. Insert the PE-Inlay into the shell.

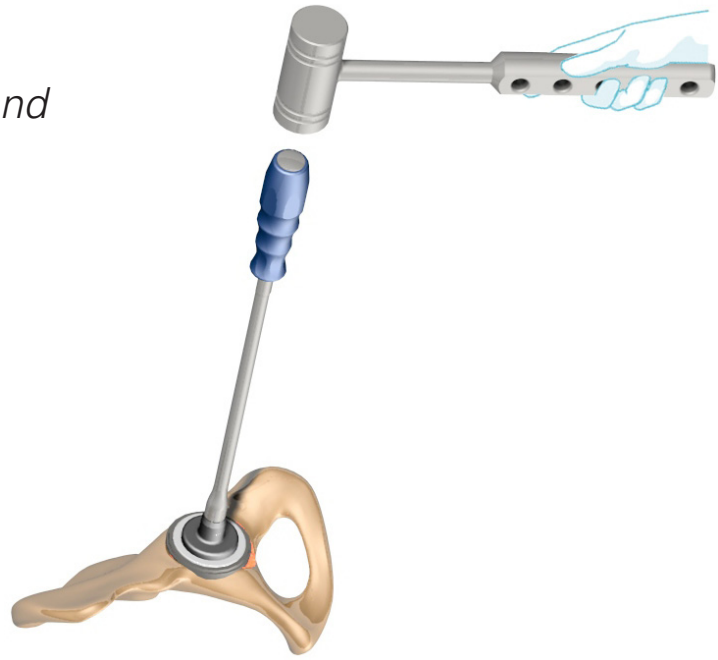
4. Drive in the PE-Inlay until the PE-Inlay is flush with the upper rim of the shell.





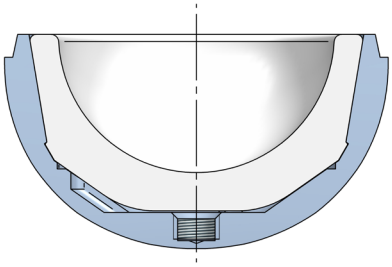
5. Surgical technique

5.8 Insertion of Xonit X-PE Inlay and Xonit-E X-PE Inlay

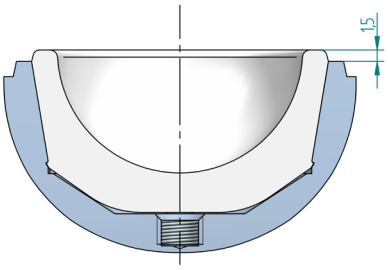


1. Select the desired Xonit Inlays (standard or dysplasia 28mm, 32mm, 36mm or 40mm).
2. Initiation of the Xonit Inlays by hand.
3. Drive in the Xonit Inlay in flush with the upper rim of the shell.

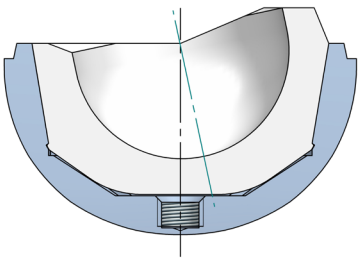
Attention!
All Xonit Inlays must be drived in flush with the upper rim of the shell. The exception case is the Xonit Inlays of the size 39/32. With this size there is an offset of 1.5mm.



Xonit Inlays standard. No offset to the upper rim of the shell.



Xonit Inlays size 39/32 with an offset of 1.5mm to the upper rim of the shell.



Xonit Inlays (dysplasia). The inlay is in flush wit the upper rim of the shell (not on collar-side).

5. Surgical technique

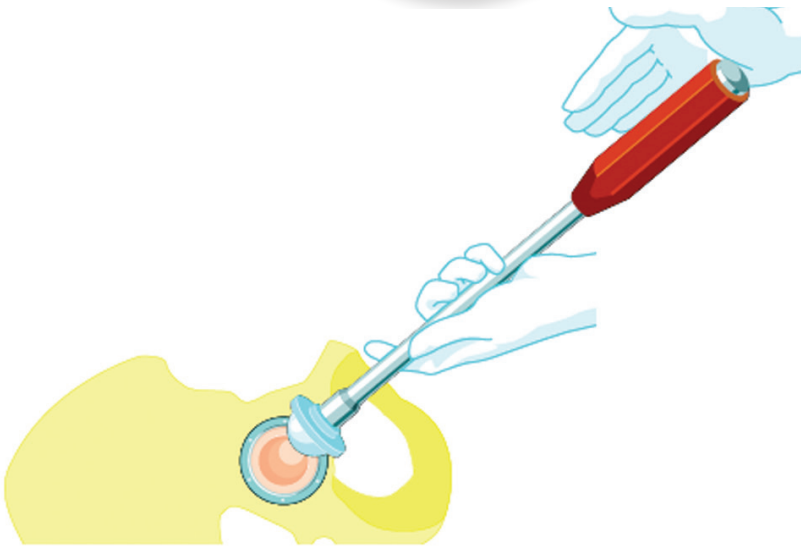
5.9 Insertion of Ceramic-Inlay

1. Insertion of Ceramic-Inlay by hand.
   Set the outer taper of the inlay to the inner taper of the cup and move the Ceramic-Inlay on the inner taper of the cup down until the inlay is on the same height like the cup.

2. Control if the Ceramic-Inlay is on the same height like the cup.
   If the Ceramic-Inlay is not inserted properly it can be removed as described in point 4.10.

   More Information about setting a Ceramic-Inlay properly in „Surgical Live Training DVD“ from Ceramtec AG.

3. Screw the ceramic finishing driver onto the handle and fix the inlay in the shell by lightly tapping on the mounted ceramic finishing driver.



5. Surgical technique

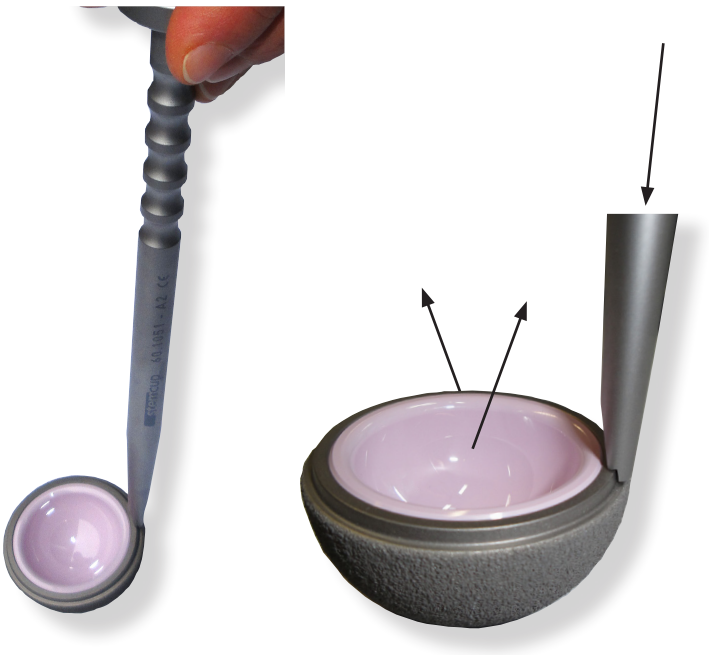
5.10 Removal of Inlays (PE, Xonit X-PE Inlay and Xonit-E X-PE-Inlay)

If the inlay replacement is required, screw in a screw in the bottom of the PE-Inlay to be replaced until the PE-Inlay detaches itself from the outer shell.

5.11 Removal of Ceramic-Inlay

1. Place the ceramic ejector punch on the rim of the cup.

2. Give it a good knock; the inlay will become loose and can be taken out by hand.



6. Ordering information

Sterility Implants
All the implants of the manufacturer which are described in this Surgical Technique are sterile. Resterilization is not allowed.

6.1 Implants

References numbers:
BSC Cup closed (370.xx.xx) / BSC Cup 3 hole (371.xx.xx) / BSC Cup 3 hole with additional HA coating and cover screws (382.xx.xx)

PE-Inlay **standard**, dysplasia / Ceramic Inlay forte, delta

BSC-Cup outer shell Ø mm	BSC Cup Ref. Nr.	PE-Inlay standard Ø 28 mm	PE-Inlay standard Ø 32 mm	PE-Inlay dysplasia Ø 28 mm	PE-Inlay dysplasia Ø 32 mm	Keramik Inlay forte Ø 28 mm	Keramik Inlay forte Ø 32 mm	Keramik Inlay delta Ø 36mm	Keramik Inlay delta Ø 40 mm
46 48	382./371./370.39.46 382./371./370.39.48	400.28.39	----------	401.28.39	----------	315.28.39	317.32.39	----------	----------
50 52	382./371./370.44.50 382./371./370.44.52	400.28.44	410.32.44	401.28.44	411.32.44	315.28.44	316.32.44	317.36.44	----------
54 56	382./371./370.48.54 382./371./370.48.56	400.28.48	410.32.48	401.28.48	411.32.48	315.28.48	316.32.48	317.36.48	317.40.48
58 60 62 64 66	382./371./370.52.58 382./371./370.52.60 382./371./370.52.62 382./371./370.52.64 382./371./370.52.66	400.28.52	410.32.52	401.28.52	411.32.52	315.28.52	316.32.52	317.36.52	317.40.52

Xonit X-PE-Inlay / Xonit-E X-PE-Inlay

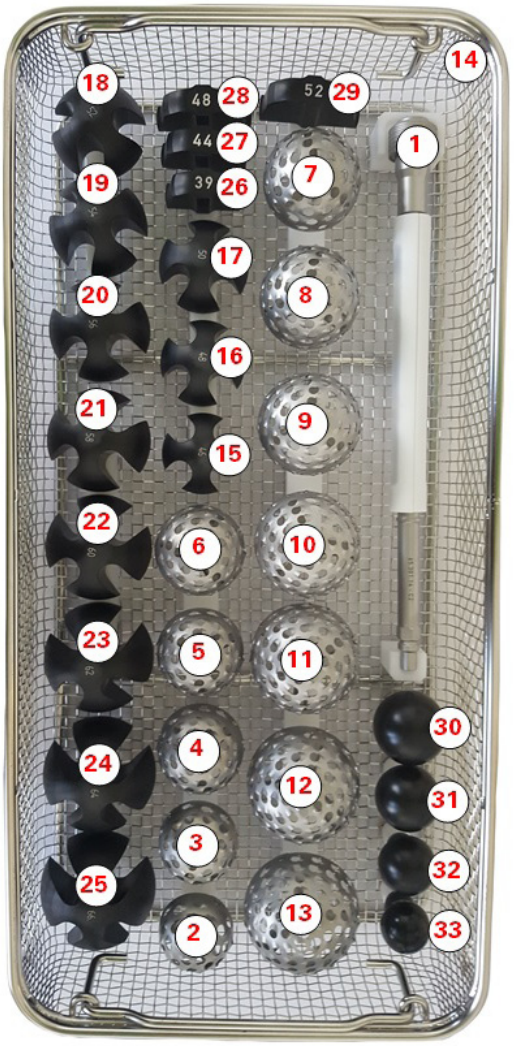
BSC-Cup outer shell Ø mm	BSC Cup Ref. Nr.	Xonit Xonit-E standard Ø 28 mm	Xonit Xonit-E standard Ø 32 mm	Xonit Xonit-E standard Ø 36 mm	Xonit Xonit-E standard Ø 40 mm	Xonit Xonit-E dysplasia Ø 28 mm	Xonit Xonit-E dysplasia Ø 32 mm	Xonit Xonit-E dysplasia Ø 36mm	Xonit Xonit-E dysplasia Ø 40 mm
46 48	382./371./370.39.46 382./371./370.39.48	420.28.39 430.28.39	420.32.39 430.32.39	----------	----------	421.28.39 431.28.39	----------	----------	----------
50 52	382./371./370.44.50 382./371./370.44.52	----------	420.32.44 430.32.44	420.36.44 430.36.44	----------	----------	421.32.44 431.32.44	----------	----------
54 56	382./371./370.48.54 382./371./370.48.56	----------	----------	420.36.48 430.36.48	420.40.48 430.40.48	----------	----------	421.36.48 431.36.48	----------
58 60 62 64 66	382./371./370.52.58 382./371./370.52.60 382./371./370.52.62 382./371./370.52.64 382./371./370.52.66	----------	----------	420.36.52 430.36.52	420.40.52 430.40.52	----------	----------	421.36.52 431.36.52	----------

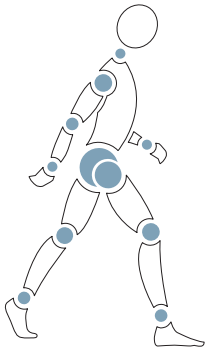
Instruments

Instruments are not sterile when they are delivered. Before use they must be cleaned according to Stemcup`s Instrument-Leaflet „Recommendations Care-Cleaning-Maintenance-Sterilization Instruments“ and sterilized in accordance with ISO 17665. Sterilization in an autoclave must be in accordance with the legal regulations and guidelines applicable in the relevant country. The correct settings are given in the instructions for use issued by the autoclave manufacturer. Stemcup`s Instrument-Leaflet „Recommendations Care-Cleaning-Maintenance-Sterilization Instruments“ is available upon request, resp. is enclosed in the instrument set. Instrument manufacturers and dealers accept no responsibility for sterilization of products by the customer.

6.2 Instruments, Tray 1

Pos.	Ref.No.	Description
1	65.301.14	Guiding shaft with quick release fastener
2	65.301.44	Pre-reamer size 44
3	65.301.46	Reamer spherical Sz. 46
4	65.301.48	Reamer spherical Sz. 48
5	65.301.50	Reamer spherical Sz. 50
6	65.301.52	Reamer spherical Sz. 52
7	65.301.54	Reamer spherical Sz. 54
8	65.301.56	Reamer spherical Sz. 56
9	65.301.58	Reamer spherical Sz. 58
10	65.301.60	Reamer spherical Sz. 60
11	65.301.62	Reamer spherical Sz. 62
12	65.301.64	Reamer spherical Sz. 64
13	65.301.66	Reamer spherical Sz. 66
14	65.301.801.01-90	Instrumentset 1 for BSC-cup (empty)
15	65.311.46	Test-cup size 46
16	65.311.48	Test-cup size 48
17	65.311.50	Test-cup size 50
18	65.311.52	Test-cup size 52
19	65.311.54	Test-cup size 54
20	65.311.56	Test-cup size 56
21	65.311.58	Test-cup size 58
22	65.311.60	Test-cup size 60
23	65.311.62	Test-cup size 62
24	65.311.64	Test-cup size 64
25	65.311.66	Test-cup size 66
26	65.331.35	Controll gauge size 39 for BSC-cup 3 hole
27	65.331.36	Controll gauge size 44 for BSC-cup 3 hole
28	65.331.37	Controll gauge size 48 for BSC-cup 3 hole
29	65.331.38	Controll gauge size 52 for BSC-cup 3 hole
30	60.1053	Impactor attachment for Inlay 40 (optional)
31	60.1043	Impactor attachment for Inlay 36 (optional)
32	60.1042	Impactor attachment for Inlay 32
33	60.1041	Impactor attachment for Inlay 28

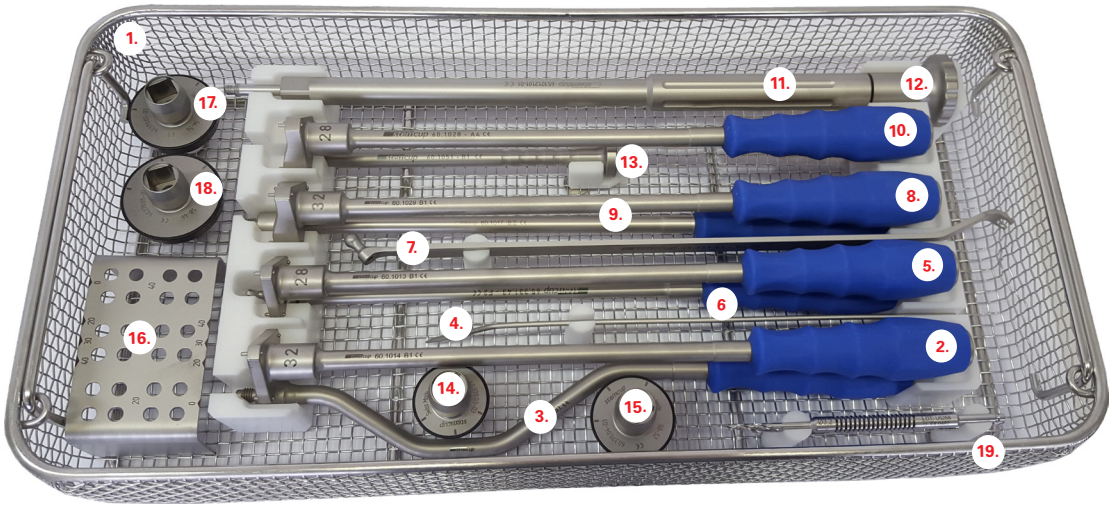




6. Ordering information

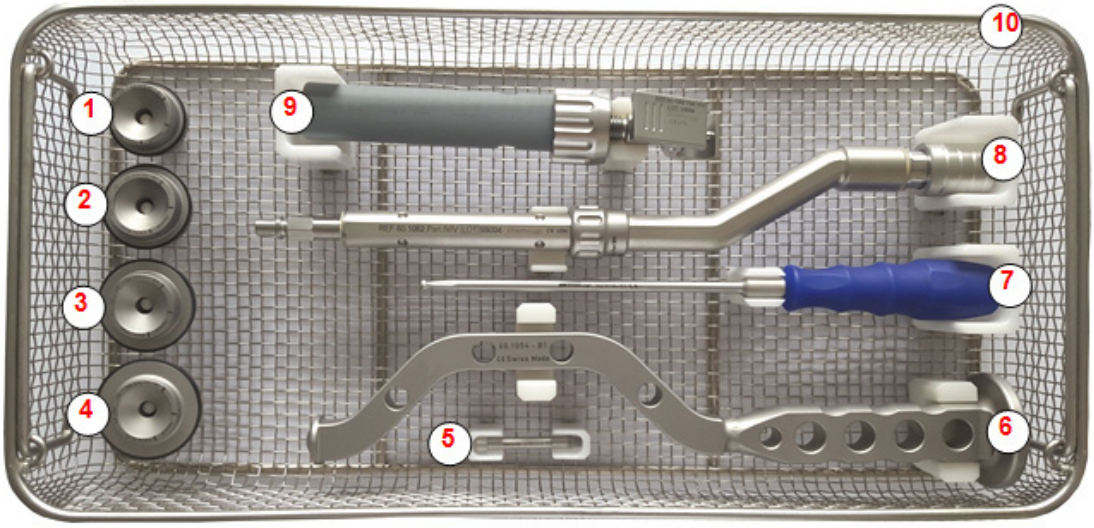
6.3 Instruments, Tray 2

Pos.	Ref.No.	Description
1	65.301.800.02-90	Instrumentset 2 for BSC cup (empty)
2	60.1014	Setting device for PE-Inlay standard 32
3	60.1018	Pusher curved
4	65.331.44	Thread measuring wire
5	60.1013	Setting device for PE-Inlay standard 28
6	65.331.43	Universal joint screw driver
7	65.331.41	Fixation for drill guide and screw holder
8	60.1029	Setting device for PE-Inlay dysplasia 32
9	60.1017	Pusher straight
10	60.1028	Setting device for PE-Inlay dysplasia 28
11	65.321.21.01-01	Setting device for BSC cup
12	65.321.21.02-02	Threaded rod for setting device for BSC-cup
13	60.1051	Ceramic-Inlay extractor
14	60.370.03	Setting device attachment size 46-48 for BSC-cup
15	60.370.04	Setting device attachment size 50-52 for BSC-cup
16	65.301.800.02.05	Holder for titanium screws
17	60.370.05	Setting device attachment size 54-56 for BSC-cup
18	60.370.06	Setting device attachment size 58-66 for BSC-cup
19	367-1316	Flexible drill short

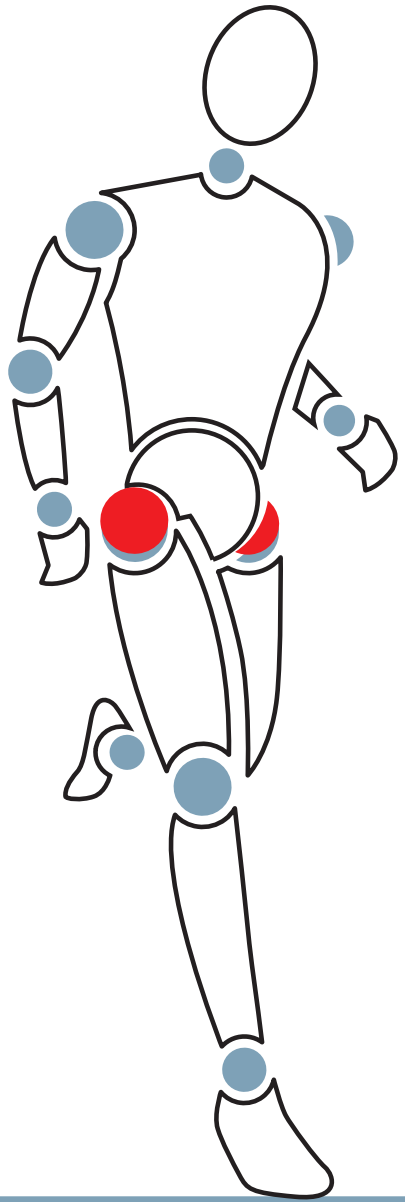


6.4 MIS-Instruments

Pos.	Ref.No.	Description
1	60.370.07	Setting device attach. to MIS-Setting instrument 46-48 for BSC-cup
2	60.370.08	Setting device attach. to MIS-Setting instrument 50-52 for BSC-cup
3	60.370.09	Setting device attach. to MIS-Setting instrument 54-56 for BSC-cup
4	60.370.10	Setting device attach. to MIS-Setting instrument 58-66 for BSC-cup
5	60.1054-01	Screw to MIS-Setting instrument
6	60.1056	MIS-Setting instrument
7	60.1062	Offset guidingshaft synthes-ao-connection
8	60.1062 handle	Handle for 60.1062
9	65.301.801.03-90	Instrumentset 3 for BSC cup



Stemcup – central and close to you!



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