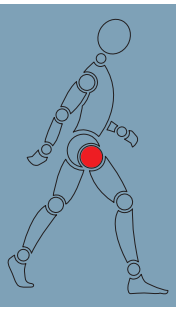
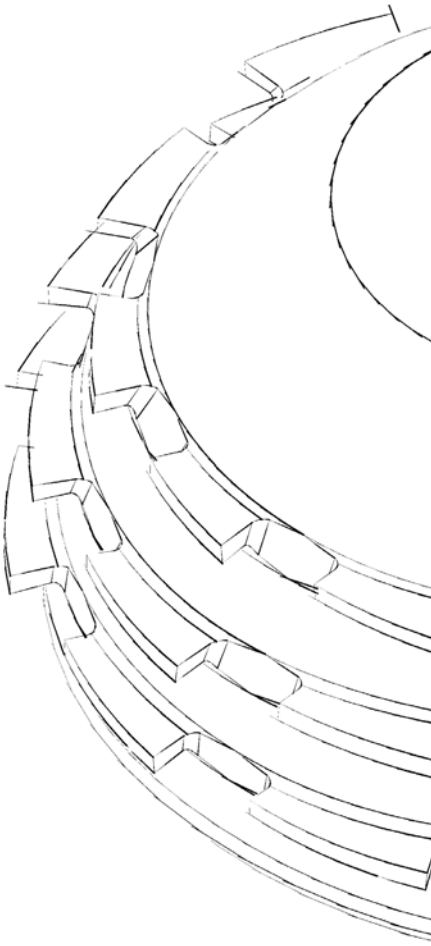
XentraX

XentraX® – Screwcup
Surgical Technique

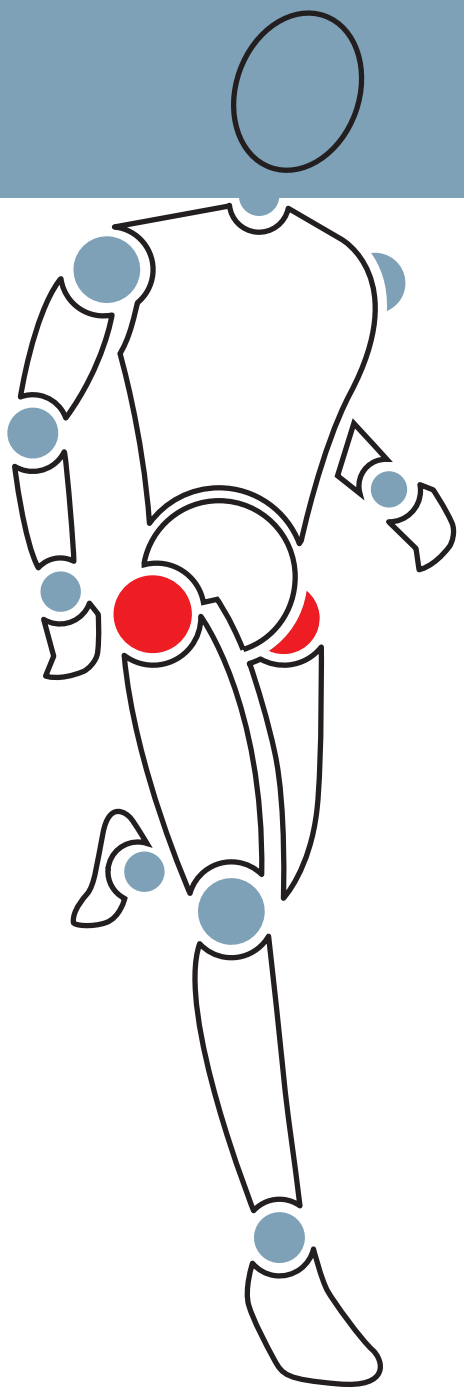




swiss design
swiss made
swiss quality

stemcup
Medical products in motion

Table of contents



1. Introduction

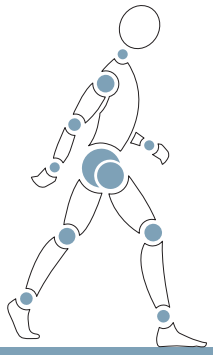
The cementless XentraX cup is equipped with a patented self-cutting trapezoid thread (Pat. DE 198 02 215 C1) on the spherical outer form. This thread type allows a substantially easier screwing of the cup with respect to comparable threaded cup systems [1].

The XentraX cup is manufactured according to ISO 5832-2. The corrudum-blasted surface of the cup ensures a good secondary stability and a quick osteointegration of the bone.

The opening at the bottom of the cup allows an optical control of the correct depth of insertion and enables, when necessary, a subsequent relining with cancellous bone material.The bottom of the cup is tightly closed with a simple-to-handle patented bottom closure of pure titanium (EP 1441673).

The assortment offers 12 sizes with diameters of 46 to 68 mm. Polyethylene, Xonit X-PE, Xonit-E X-PE and Ceramic-Inlays are available. It's possible to use ballheads with 36mm diameter from cup size 50 with Ceramic-Inlays. From cup size 54 it's possible to use 40 ballheads in ceramic. The bigger ballheads increase the ROM of the cup, which ends up to more mobility for the patient.

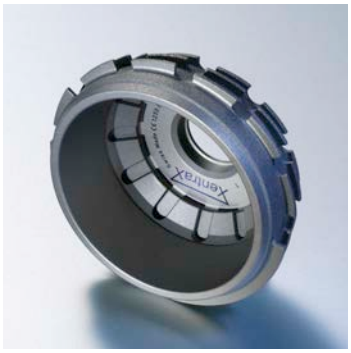
[1] Effenberger H et al. Retraction behavior of screw pans Journal of Orthopedics and Trauma Surgery 2008; 146:185-193



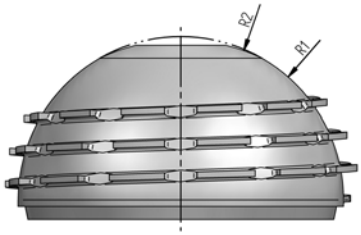
2. System description

2.1 Prostheses design

- 12 cup sizes of ø 46 - 68 mm
- Material: pure titanium / ISO 5832-2
- spherical outer form
- negative trapezoid thread
- orundum-blasted surface roughness Ra 4 - 6 µm
- opening at the bottom of the cup for supervision and relining with cancellous bone material. Closable with bottom closure of pure titanium.



XentraX cup



spherical shape

2.2 Tribological pairings

Due to the special shape of the XentraX cup the thickness of the PE-Inlays are bigger than corresponding competitive products. Because of the special shape it's also possible to use bigger ballheads in smaller cups if a ceramic tribological pairing is designated.

	Ø28	Ø32	Ø36	Ø40
PE-Inlay standard	size 46-68	size 50-68	———	———
PE-Inlay dysplasia	size 46-68	size 50-68	———	———
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-Inlays	size 46-68	size 46-68	size 50-68	size 54-68

UHMWPE Inlay

Xonit X-PE Inlay

Xonit-E X-PE Inlay (with Vitamin E as antioxidant)

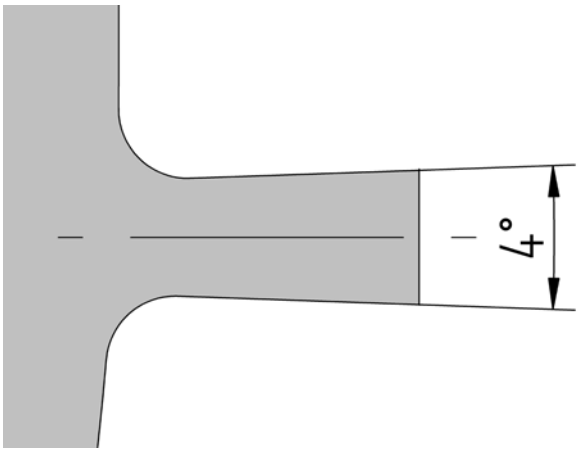
Ceramic-Inlay

2. System description

2.3 Trapezoid thread

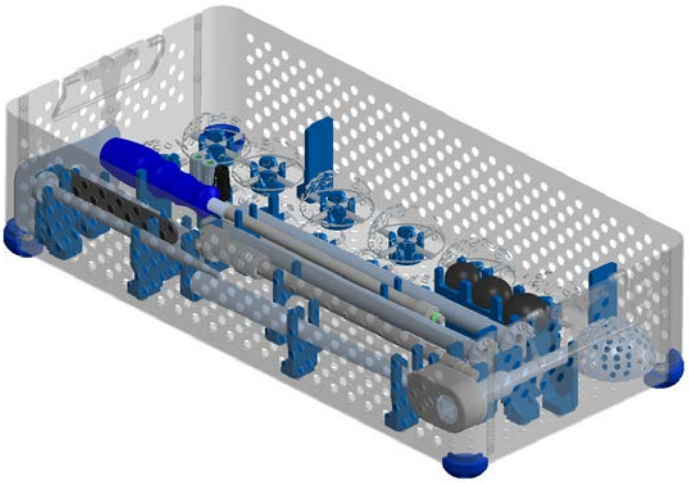
The patented self-cutting trapezoid thread allows to screw the cup on with slight effort [1]. The thread design prevents jamming of the cup. This also applies to sclerotic bone.

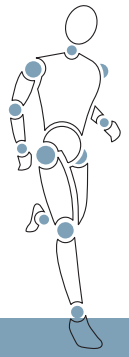
The "set point" (bone-implant contact) is reached when it feels considerably harder to continue [1]. An over-screwing of the cup is almost impossible.



2.4 Instrumentation

Well-arranged instrumentation is simple to handle and easy to clean. It allows an efficient, safe and precise following of individual surgery steps. An exact correspondence between the instrumentation and the implant enables precise implantation and a reproducible transfer of the existing preoperative planning.



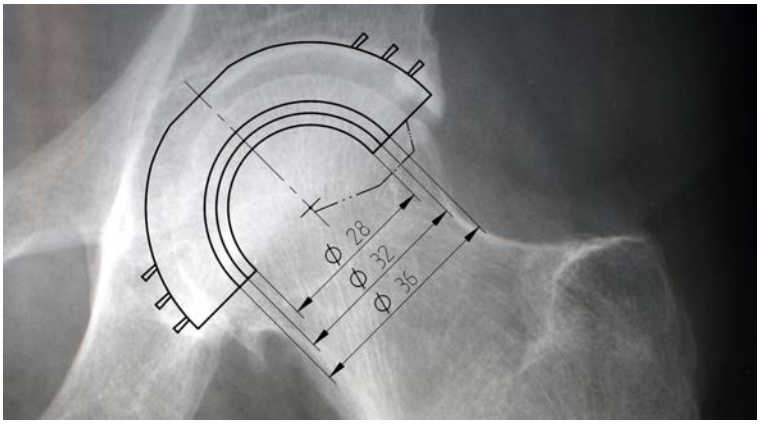


3. Preoperative Planning
4. Indications / Contraindications / E-IFU

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)

4. Indications / Contraindications / E-IFU

- 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.

4.2 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

4. Indications / Contraindications / E-IFU

4.2.1 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.

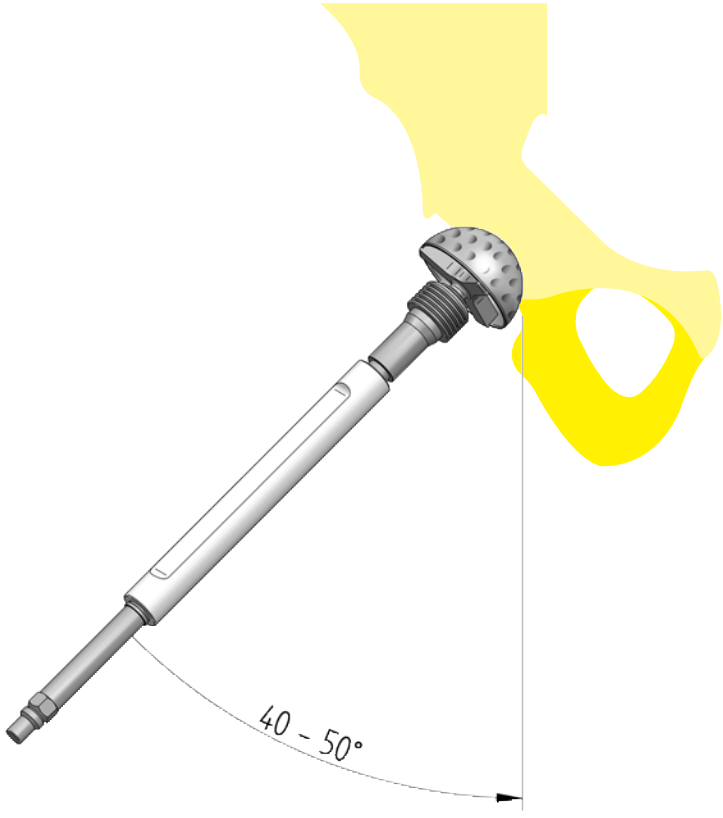
Before a user first uses a specific medical device of Stemcup a printed version of the specific IFU is provided. In the event of a revision of the IFU every customer will receive it in a printed version.

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.

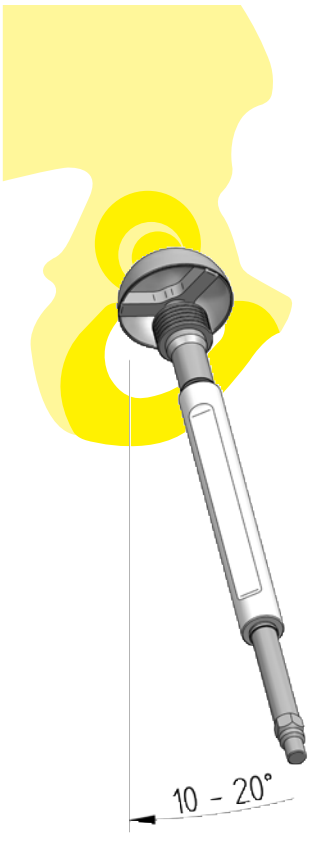
5. Surgical Technique

5.1 Guide shaft & Reamer

Ream the acetabulum stepwise to the suitable cup size.



Entry angle of the cup



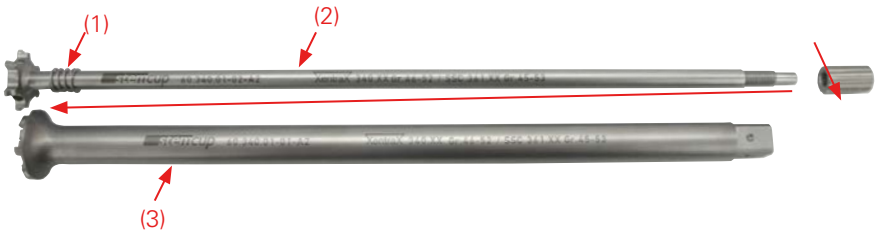
Anteversion / Retroversion angle

5. Surgical Technique

5.2 Setting instrument fitting

1. At first the spring (1) have to slide over the interlock shaft (2). Then the interlock shaft have to insert to the turn in shaft (3) and the locking screw (4) is screwed on the interlock shaft.

1.



2. The locking screw have to be screwed so far that the interlock shaft isn`t sunk in the screw. Now the setting instrument is ready for use!!

2.

3. The XentraX screwcup is placed on the table and the setting instrument is put into the cup.

4. By slightly turning and pressing of the setting instrument, the turn in shaft snaps into the pre-milled grooves of the cup.

5. The locking screw is tightened and the cup is ready for screwing.

3.

4.

5.

5. Surgical technique

5.3 Setting instrument removal

1. For releasel of the setting instrument the locking screw have to be resolved.
   For release of the screw the box spanner is pushed over the locking screw and is resolved with a left-hand turn.

2. For release the setting instrument the interlock shaft have to countersink slightly in the locking screw.

3. Now the box spanner are pushed over the square of the turn in shaft to the locking screw, thereby the shaft is fitted to the screw.

4. With a little left-hand oder right-hand turn at the box spanner, the setting instrument is solved of the cup.

5. If the locking screw is unscrewed too far, the setting instrument cannot be resolved.

1.

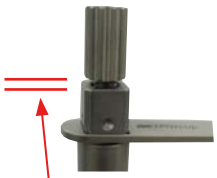
2.

The interlock shaft have to countersunk slighty into the screw.
The screw have to be solved ca. 3 rotations!

3.

The turn in shaft have to be pulled out on the locking screw thereby the setting instrument can be solved.

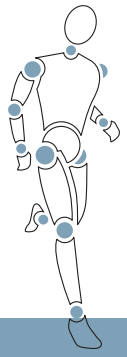
4.



If there is a distance between the locking screw and the turn in shaft, the setting instrument cannot be resolved.

5.

The locking screw is unscrewed too far. Thereby the setting insturment cannot be resolved.



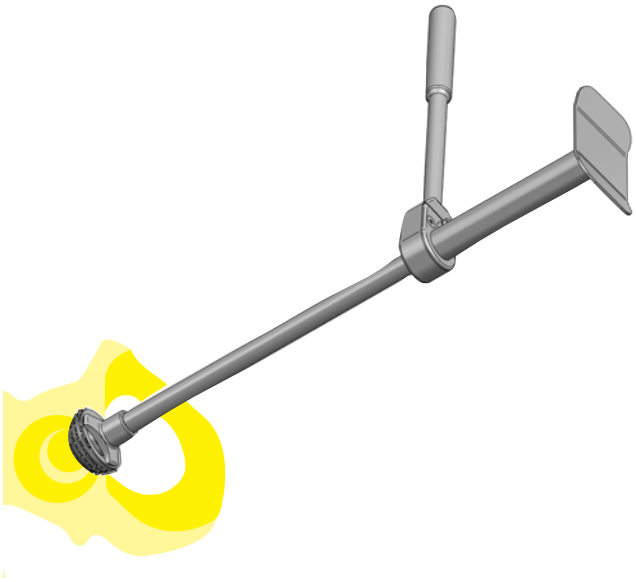
5. Surgical technique

5.4 Screwing of the implant

Screw in the implant with the help of the ratchet until the cup body fits tightly against the pre-reamed acetabular bed.

Loosen the screwing instrument:
See Point 4.2.

Pull out the instrument and check the screwing depth. Additional screwing or relining of the acetabulum may be required.



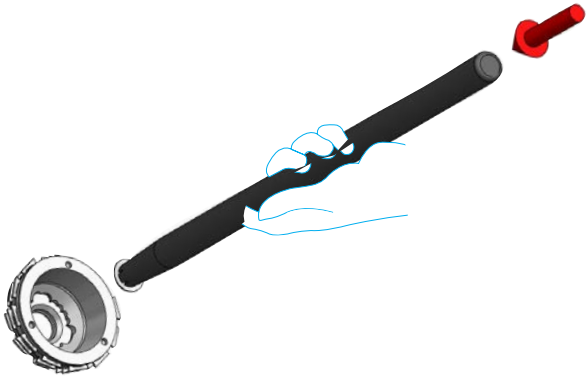
5.5 Insertion of the bottom closure

1. Place the bottom closure on the pusher.
2. Insert the bottom closure into the cup. Fix the bottom closure by lightly pressing on the pusher or slightly rotating it.

Attention!
Don‘t bang with a hammer on the pusher!! (Abrasion of the setting instrument)

1.

2.



5. Surgical technique

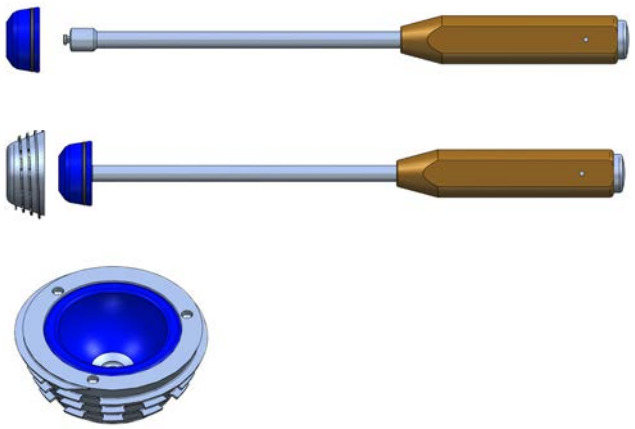
5.6 Test Inlay

By means of the used test inlay can be performed a trial reduction.

Standard test inlays for all possible diameters of ballheads are available.

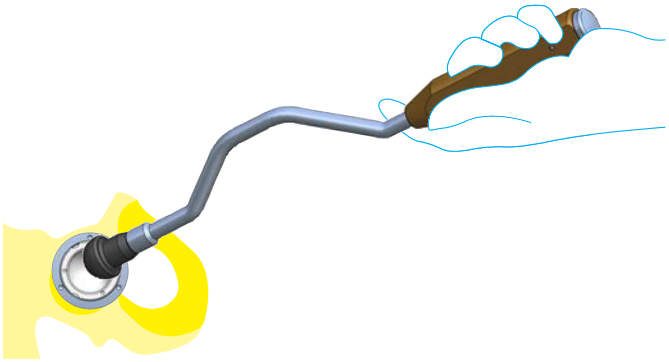
Colour code test inlays:

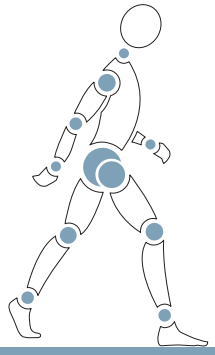
Ø28	Ø32	Ø36	Ø40
green	blue	grey	black



5.7 Insertion of PE-Inlay

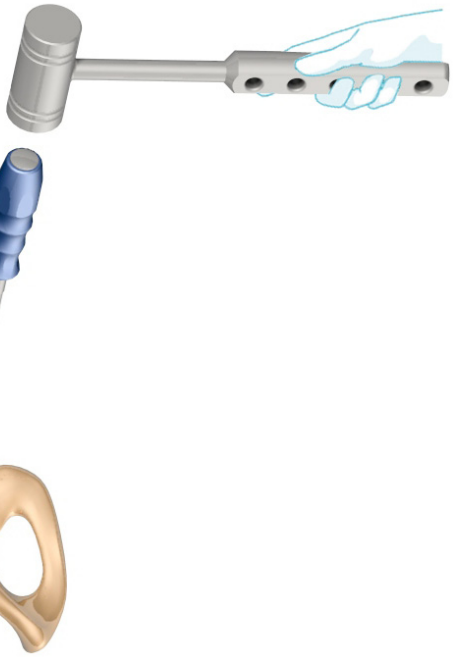
1. Selection of the desired PE-Inlay.
2. Inseration of the PE-Inlay by hand. The position of the edge increase of the dysplasia inlays are freely selectable.
3. Screw the finishing head onto the pusher and fix the PE-Inlay in the cup by tapping on the mounted pusher to make sure that the inlay is flush with the upper rim of the shell.





5. Surgical technique

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

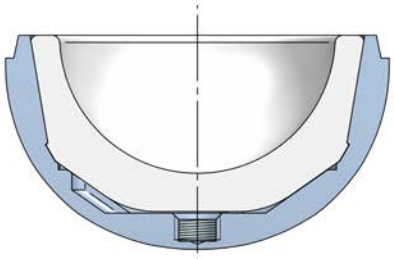


1. Select the desired Xonit X-PE-Inlay / Xonit-E X-PE-Inlay (standard or dysplasia, 28mm, 32mm, 36mm or 40mm).

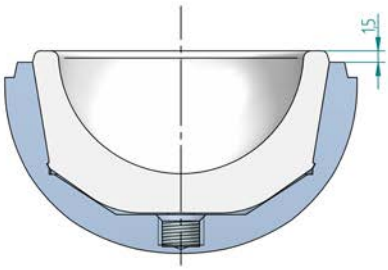
2. Inseration of the Xonit X-PE-Inlay / Xonit-E X-PE-Inlay by hand.

3. Drive in the Xonit X-PE-Inlay / Xonit-E X-PE-Inlay in flush with the upper rim of the shell.

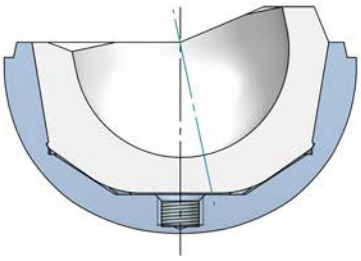
Attention!
All PE Xonit (Xonit-E) X-PE Inlays must be drived in flush with the upper rim of the shell. The exception case are the Inlays of the size 39/32. With this size there is an offset of 1.5mm.



PE, Xonit (Xonit-E) X-PE Inlays standard. No offset to the upper rim of the shell.



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



Dysplasia Inlays. The Inlay is in flush wit the upper rim of the shell (not on collar-side).

5. Surgical technique

5.9 Inseration 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.

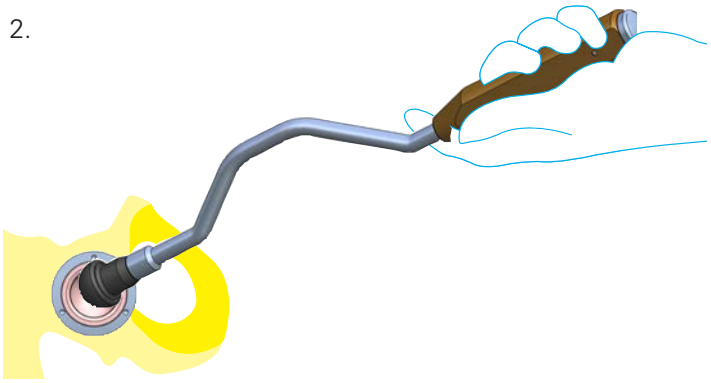
2. Control if Ceramic-Inlay is on the same height like the cup.
   If the Ceramic-Inlay is not inserted properly it can be removed as described in point 4.10.

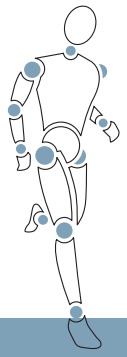
   More Information about setting a Ceramic-Inlay properly in „Surgical Live Training DVD“ from Ceramtec AG.

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

1.

2.

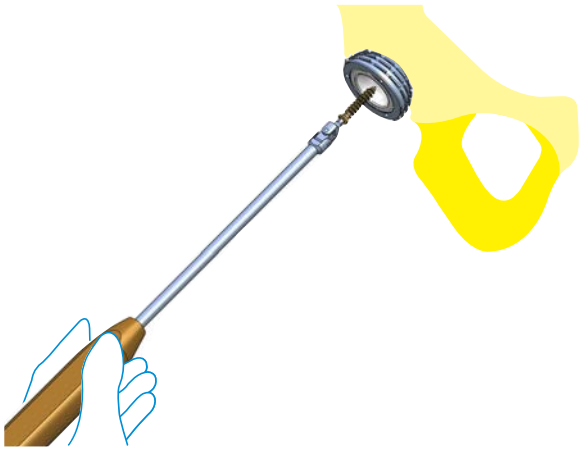




5. Surgical Technique

5.10 Removal of 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.



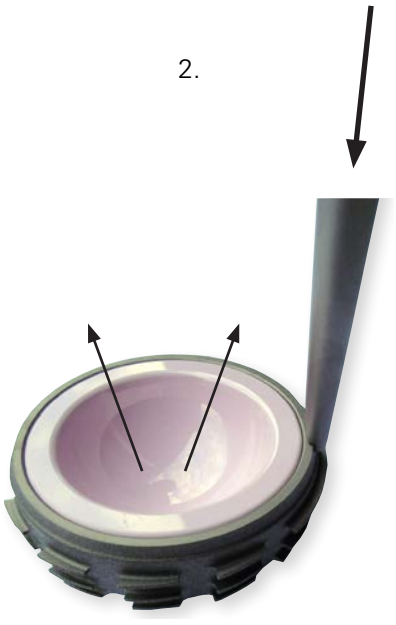
5.11 Removal of Ceramic-Inlay

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.

1.

2.



6. Ordering information

Instructions for use for implants

The implants are delivered sterile and/or non-sterile. The instructions for use „BPZ Implants DE“ and/or „BPZ INST IMP„ must be consulted before use. The E-IFU are available electronically on the Stemcup homepage. A printed version of the IFU can be requested at any time. The delivery takes 1 to 7 days.

6.1 Implants

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

XentraX Cup outer diameter Ø mm	XentraX 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	Ceramic-Inlay Ø 32 mm	Ceramic-Inlay Ø 36mm	Ceramic-Inlay Ø 40 mm
46 48	340.39.46 340.39.48	400.28.39	----------	401.28.39	----------	317.32.39	----------	----------
50 52	340.44.50 340.44.52	400.28.44	410.32.44	401.28.44	411.32.44	317.32.44	317.36.44	----------
54 56	340.48.54 340.48.56	400.28.48	410.32.48	401.28.48	411.32.48	317.32.48	317.36.48	317.40.48
58 60 62 64 66 68	340.52.58 340.52.60 340.52.62 340.52.64 340.52.66 340.52.68	400.28.52	410.32.52	401.28.52	411.32.52	317.32.52	317.36.52	317.40.52

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

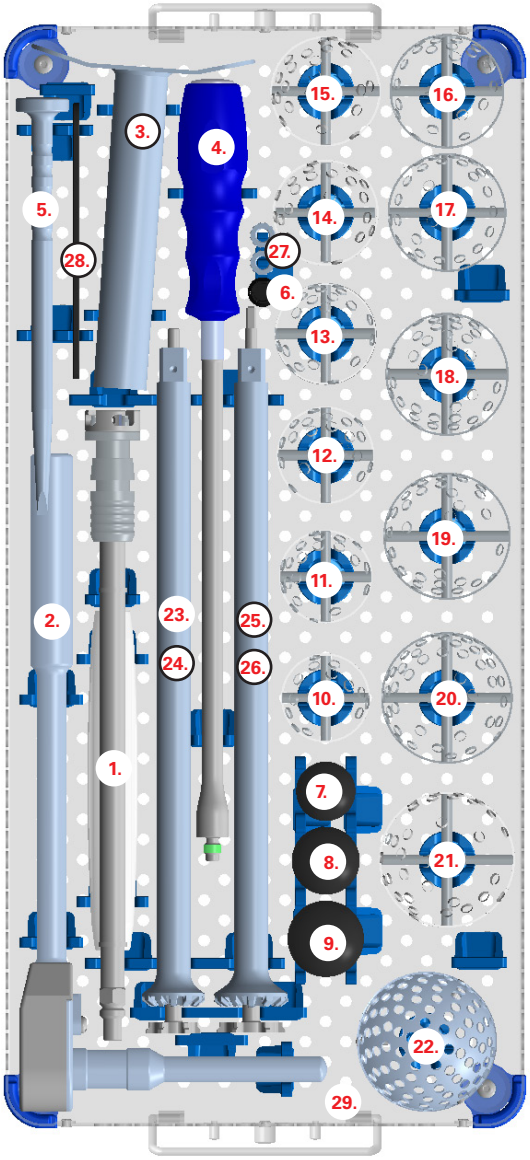
XentraX Cup outer diameter Ø mm	XentraX Cup Ref. Nr.	Xonit Xonit-E standard Ø 28 mm	Xonit Xonit-E standard Ø 32 mm	Xonit Xonit-E standard Ø 36 mm	Xonit Xonit-E standard Ø 40 mm	Xonit Xonit-E dysplasia Ø 28 mm	Xonit Xonit-E dysplasia Ø 32 mm	Xonit Xonit-E dysplasia Ø 36mm	Xonit Xonit-E dysplasia Ø 40 mm
46 48	340.39.46 340.39.48	420.28.39 430.28.39	420.32.39 430.32.39	----------	----------	421.28.39 431.28.39	----------	----------	----------
50 52	340.44.50 340.44.52	----------	420.32.44 430.32.44	420.36.44 430.36.44	----------	----------	421.32.44 431.32.44	----------	----------
54 56	340.48.54 340.48.56	----------	420.32.48 430.32.48	420.36.48 430.36.48	420.40.48 430.40.48	----------	421.32.48 431.32.48	421.36.48 431.36.48	----------
58 60 62 64 66 68	340.52.58 340.52.60 340.52.62 340.52.64 340.52.66 340.52.68	----------	420.32.52 430.32.52	420.36.52 430.36.52	420.40.52 430.40.52	----------	421.32.52 431.32.52	421.36.52 431.36.52	----------

Instructions for use for instruments - according to EN ISO 17664:2017

The instruments are delivered non-sterile. Before using non-sterile products, please consult the recommendations for cleaning, maintenance, packaging, sterilization and storage of Stemcup Medical Products AG. The instructions for use „BPZ INST IMP" are available electronically on the Stemcup homepage. A printed version of the IFU can be requested at any time. Delivery takes 1 to 7 days. Instrument manufacturers and dealers do not take responsibility for the sterilization of products by the purchaser. The legal regulations for the reprocessing of medical devices valid in your country must be observed. In countries where stricter requirements apply, these must be observed.

6.2 Instruments

Pos.	Ref	Description
1	60.1080	Guide shaft with snap closure
2	60.213.21	Ratchet
3	60.213.22	Handle with supporter
4	60.1017	Pusher, straight
5	60.1051	Ceramic-insert extractor
6	60.1033	Setting device attachment for cover to 60.1017 /60.1018
7	60.1041	Finishing head for insert 28
8	60.1042	Finishing head for insert 32
9	60.1043	Finishing head for insert 36
10	65.302.44	Pre-reamer Size 44
11	65.302.46	Spherical reamer size 46
12	65.302.48	Spherical reamer size 48
13	65.302.50	Spherical reamer size 50
14	65.302.52	Spherical reamer size 52
15	65.302.54	Spherical reamer size 54
16	65.302.56	Spherical reamer size 56
17	65.302.58	Spherical reamer size 58
18	65.302.60	Spherical reamer size 60
19	65.302.62	Spherical reamer size 62
20	65.302.64	Spherical reamer size 64
21	65.302.66	Spherical reamer size 66
22	65.302.68	Spherical reamer size 68
23	60.340.07-01	Turn in shaft for setting device 46-52 V2
24	60.340.07-02	Interlock shaft for setting device 46-52 V2
25	60.340.08-01	Turn in shaft for setting device 54-68 V2
26	60.340.08-02	Interlock shaft for setting device 54-68 V2
27	60.340.03	Locking screw for setting device –> 2 Pieces
28	60.340.09	Box spanner for setting device V2
29	60.340.801.01	Instrumentset / Base tray

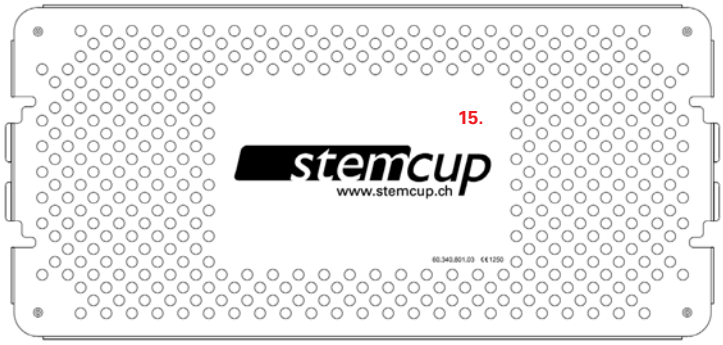


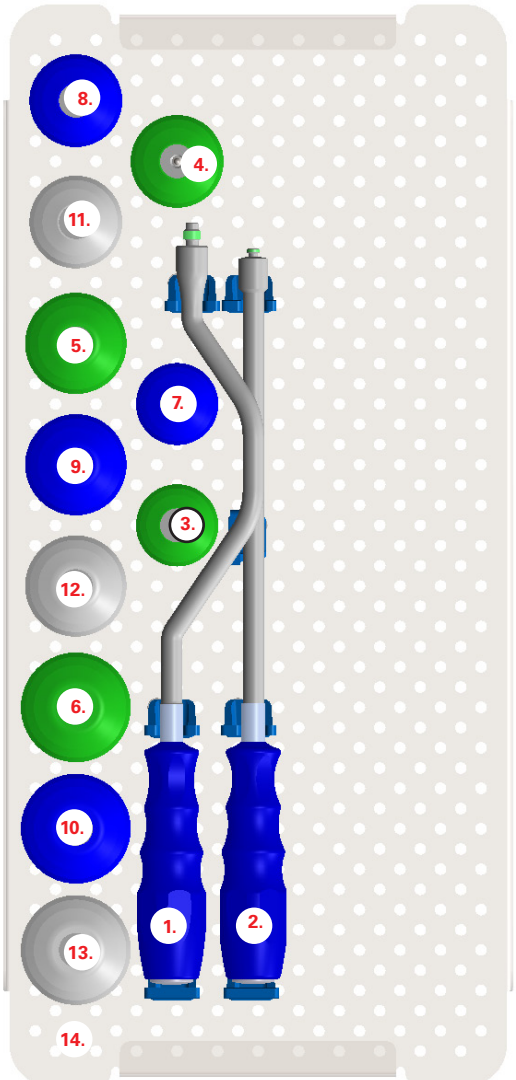
6. Ordering information

6.3 Instruments optional

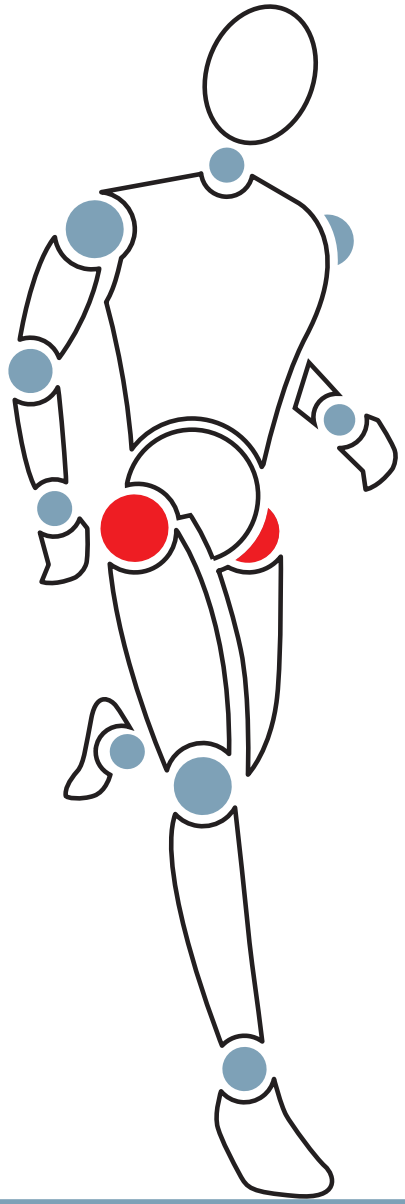
Pos.	Ref	Description
1	60.1018	Pusher curved
2	60.1032	Setting device for testinsert
3	60.28.39	Trial liner 39/28
4	60.28.44	Trial liner 44/28
5	60.28.48	Trial liner 48/28
6	60.28.52	Trial liner 52/28
7	60.32.39	Trial liner 39/32
8	60.32.44	Trial liner 44/32
9	60.32.48	Trial liner 48/32
10	60.32.52	Trial liner 52/32
11	60.36.44	Trial liner 44/36
12	60.36.48	Trial liner 48/36
13	60.36.52	Trial liner 52/36
14	60.340.801.02	Instrumentset / Insert tray*
15	60.340.801.03	Instrumentset / lid to base tray*

* The Insert tray (14) and the lid to base tray (15) are not optional. Those belong to the standard instrumentset.





Stemcup – central and close to you!



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