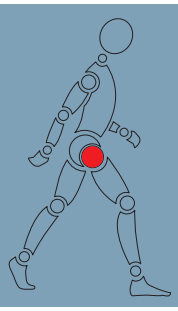
OVER 30 YEARS OF EXPERIENCE IN MEDICAL TECHNOLOGY

30 YEARS

BSC Macro Cup
Surgical Technique

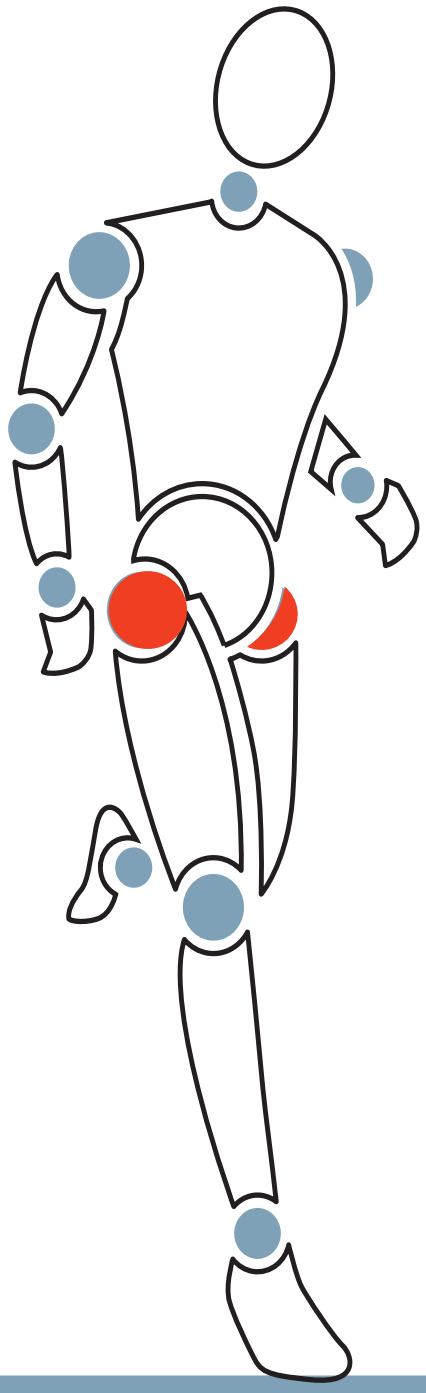


swiss design
swiss made
swiss quality

stemcup

Medical products in motion

Table of contents




VPS Coating

1. Introduction

The reliable BSC Hip Cup system has been expanded with a macrostructured BSC Macro cup variant.
The new BSC Macro cup version, is a pressfit cup slightly flattend at the pole and 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. The good secondary stability is achieved by a rough macrostructured surface, so that a good osteointegration is ensured.

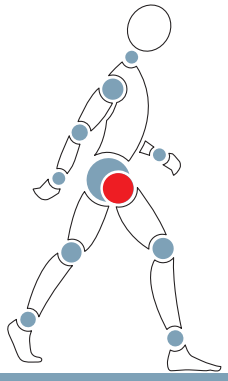
Complementary to the closed BSC Macro Cup, versions with 3 screw holes, 6 screw holes (Multihole) and with additonal screw options through the cup rim (clauster hole) are available.

The BSC Cup is available with an added titanium-hydroxylapatite-coating to enhance the osseointegrative ability.

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 range of motion.

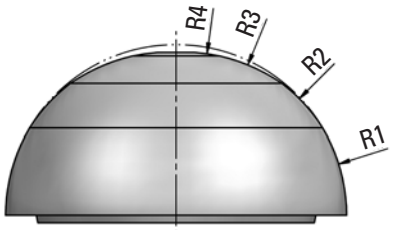


2. System description

2.1 Prosthesis design

- 11 cup sizes of Ø 46 - 66 mm
- Closed type, 3 hole type, 6 hole type (Multihole) and Clusterhole type with screw connection possibility on cup rim
- Material: Titan ISO 5832-3
- in addition with titanium plasma coating (HA) 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 Ceramic-Inlay

BSC-Macro Cup cementless



BSC pressfit cup with different radiuses

2.2 Cup Inlays

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

UHMWPE Inlay

Xonit X-PE Inlay

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

Ceramic-Inlay

2. System description

2.3 Cancellous bone screw

Material: Ti6Al4V / ISO 5832-3 (sterile)

300.65.20-S	Cancellous bone screw 6,5x20 mm
300.65.25-S	Cancellous bone screw 6,5x25 mm
300.65.30-S	Cancellous bone screw 6,5x30 mm
300.65.35-S	Cancellous bone screw 6,5x35 mm
300.65.40-S	Cancellous bone screw 6,5x40 mm

Material: Ti6Al4V / ISO 5832-3 (non sterile)

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

2.4 Coverscrews

Material: Ti6Al4V / ISO 5832-3 (sterile)

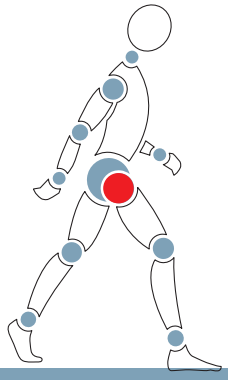
30.08	Coverscrew M8
30.10	Cover M10

2.5 Corticalis screw

Material: Ti6Al4V / ISO 5832-3 (non sterile)

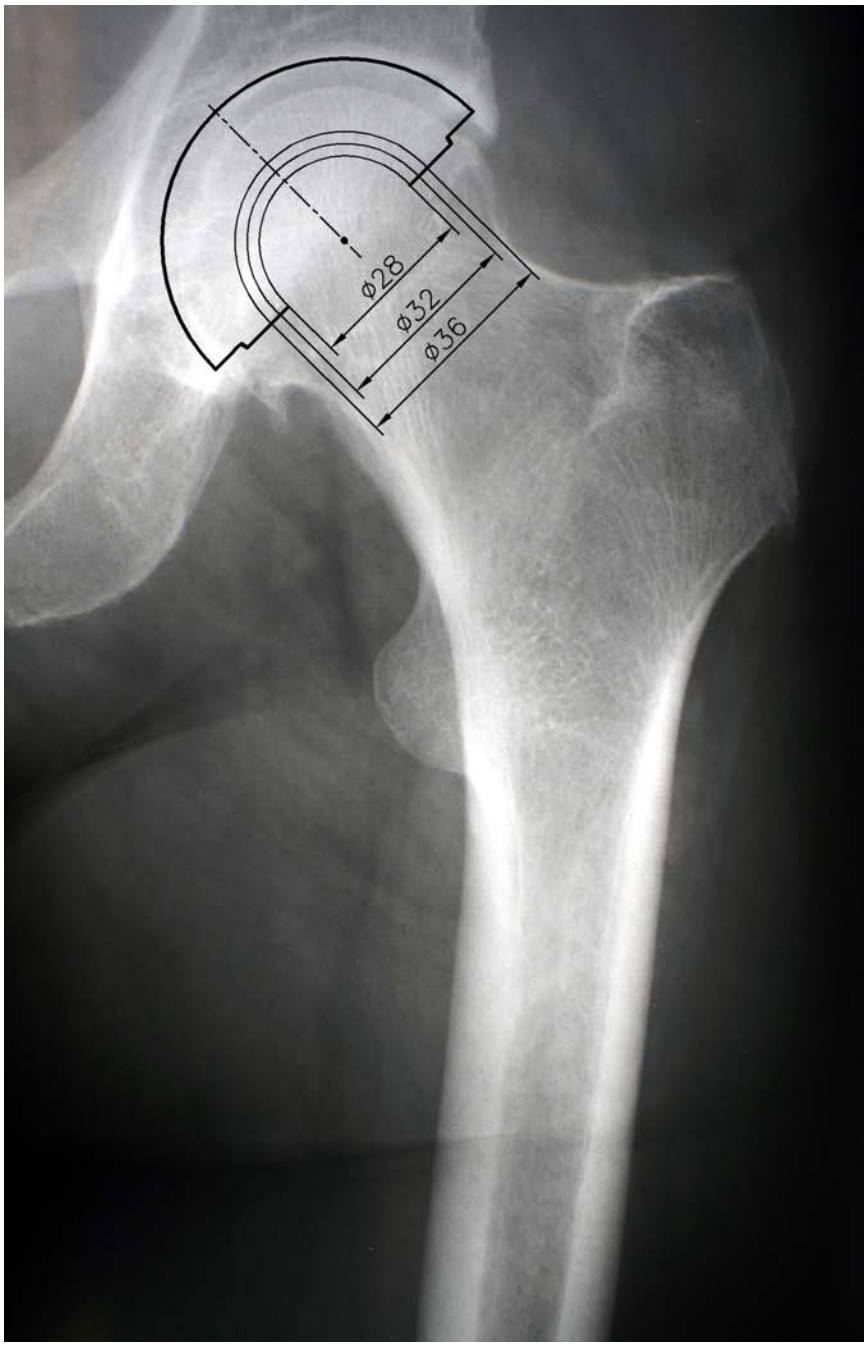
300.67.20	Corticalis screw 4,5x20 mm
300.67.30	Corticalis screw 4,5x30 mm
300.67.40	Corticalis screw 4,5x40 mm

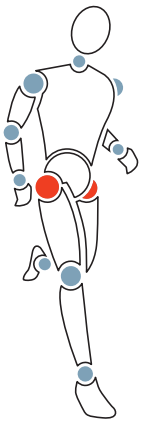
300.35.20	Corticalis screw 3.5x20 mm
300.35.22	Corticalis screw 3.5x22 mm
300.35.24	Corticalis screw 3.5x24 mm
300.35.26	Corticalis screw 3.5x26 mm
300.35.28	Corticalis screw 3.5x28 mm
300.35.30	Corticalis screw 3.5x30 mm
300.35.32	Corticalis screw 3.5x32 mm
300.35.34	Corticalis screw 3.5x34 mm
300.35.36	Corticalis screw 3.5x36 mm
300.35.38	Corticalis screw 3.5x38 mm
300.35.40	Corticalis screw 3.5x40 mm
300.35.42	Corticalis screw 3.5x42 mm
300.35.44	Corticalis screw 3.5x44 mm
300.35.45	Corticalis screw 3.5x45 mm
300.35.46	Corticalis screw 3.5x46 mm
300.35.48	Corticalis screw 3.5x48 mm
300.35.50	Corticalis screw 3.5x50 mm
300.35.55	Corticalis screw 3.5x55 mm
300.35.60	Corticalis screw 3.5x60 mm



3. Preoperative planning

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





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

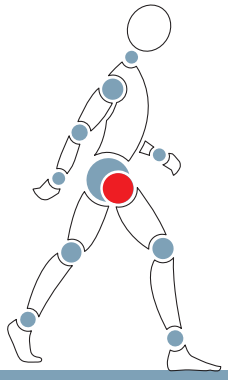
It follows, from the above statements, that a prosthesis is indicated in cases where some of the following basic conditions are fulfilled:

- Severe hip joint wear due to degenerative, post-traumatic, or rheumatoid arthritis.
- Condition resulting from previous surgery, e.g. osteosynthesis, joint reconstruction, arthrodesis, hemiarthroplasty, or total hip replacement.
- The selected patient's joint is anatomically and structurally/qualitatively suited for the reception and implantation of a prosthesis.
- Fracture or avascular necrosis of the femoral head.

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

The following circumstances require special attention, as they 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
- severe 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 Contraindications

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

Expanded contraindications: BIOLOX®delta Insert

The joint may not luxate during movement or sub luxate 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 below a value of 10-20°. Outside this range, there are restrictions in movement, which can lead to subluxation, and/or dislocations of the femoral head from the BIOLOX®delta insert.

For a cup position, which lies outside the above-mentioned values, a BIOLOX®delta Insert must not be used. For acetabular shells in retroversion, a BIOLOX®delta Insert 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 Insert associated with increased ceramic debris. Excessive ceramic debris can lead to adverse tissue reaction, loosening 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.

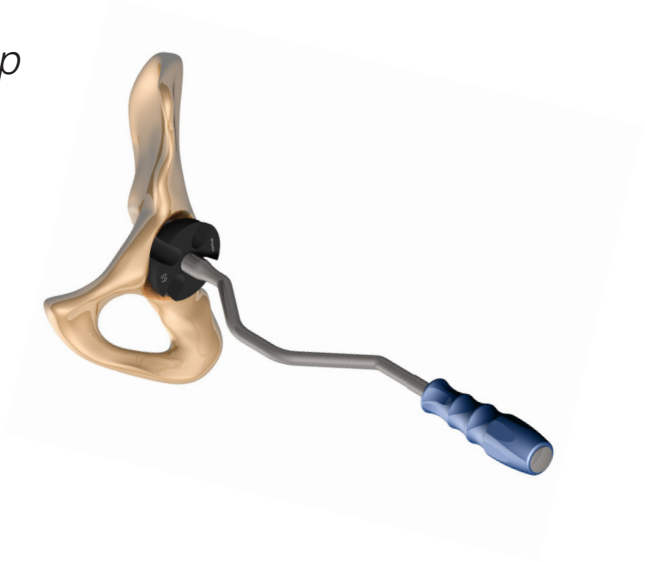
The reamer will be insert in the Guiding shaft with quick release fastener (straight or curved version).

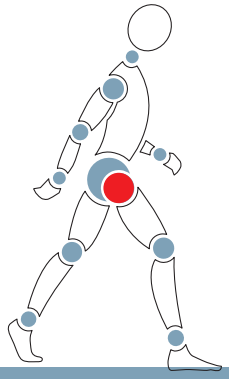
Anteversion / Retroversion angle

Entry angle of the cup

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 BSC Macro Impactor

Screw in the Impactor BSC Macro straight in the BSC Macro Cup.

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

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 (Cancellous bone screw/ Corticalis screw)

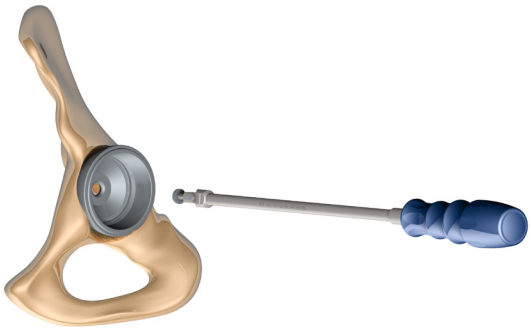
Fix the screw with a screw holder and screw it in with a cardan screwdriver.
Screw holes which are not used, can be closed with cover screws.

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

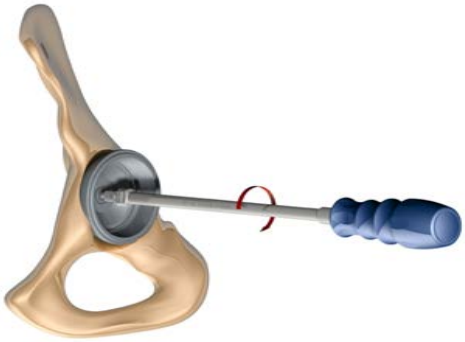
5. Surgical technique

5.6 Cover M10 *(optional)*

1. Put the cover M10 onto the screwdriver.



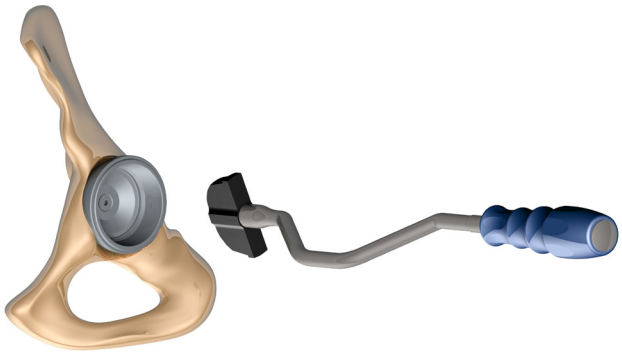
2. Screw the Cover M10 in the large M10x1 hole on the bottom of the BSC Macro Cup.

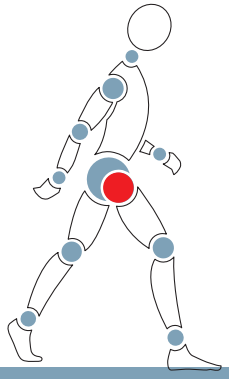


5.7 Master gauge

1. Screw a suitable master gauge onto the handle.

2. Check by rotating the master gauge if the screws are inserted deep enough.

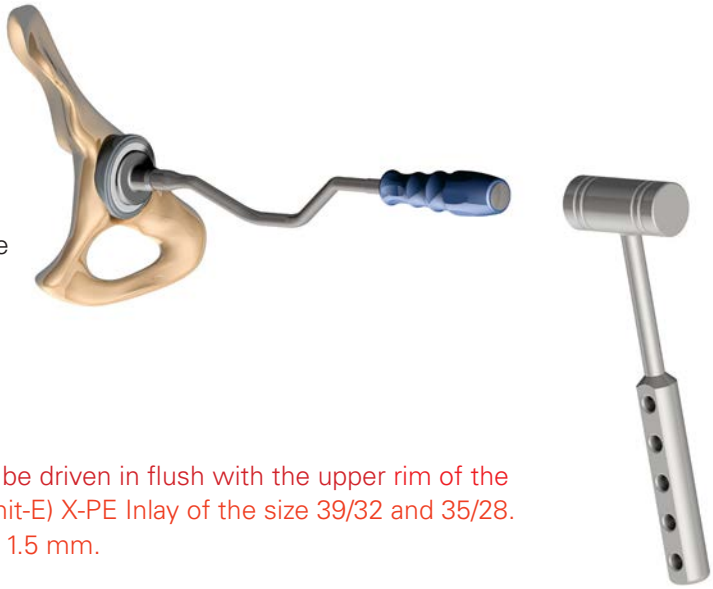




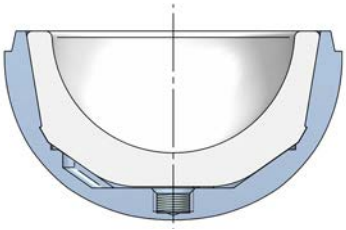
5. Surgical technique

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

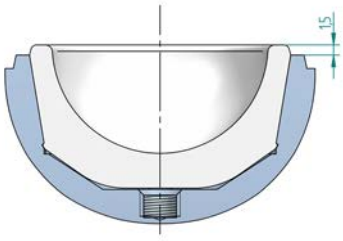
1. Select the needed Inlay (standard or dysplasia, 28mm, 32mm, 36mm or 40mm).
2. Apply the PE / X-PE Inlay by hand.
3. Drive in the PE / X-PE Inlay in flush with the upper rim of the cup.



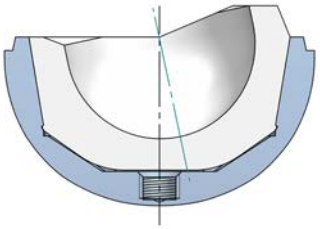
Attention!
All Xonit (Xonit-E) X-PE Inlays must be driven in flush with the upper rim of the cup. The exception is the Xonit (Xonit-E) X-PE Inlay of the size 39/32 and 35/28. With this sizes there is an offset of 1.5 mm.



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



Xonit Inlay sizes 39/32 and 35/28 have an offset of 1.5mm to the upper rim of the cup.



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

5. Surgical technique

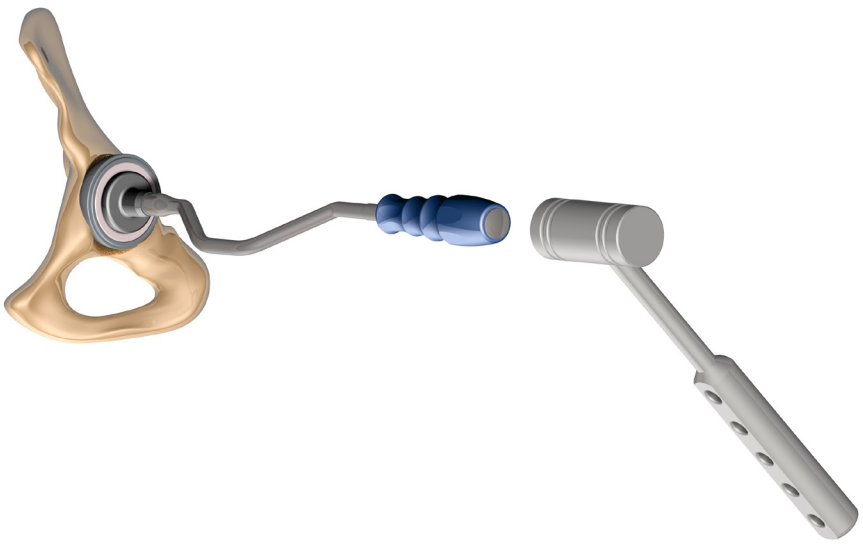
5.9 Insertion of Ceramic Inlay

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 5.11.

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

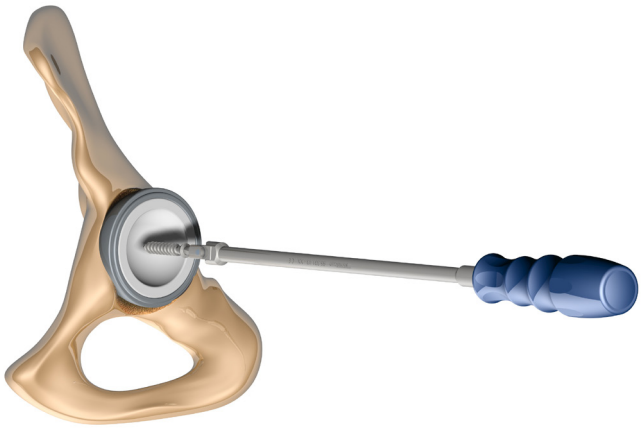
3. Screw the ceramic finishing driver onto the handle and fix the inlay in the cup by slightly tapping on the mounted ceramic finishing driver.



5. Surgical technique

5.10 Removal of PE Inlay, Xonit X-PE Inlay and Xonit-E X-PE Inlay

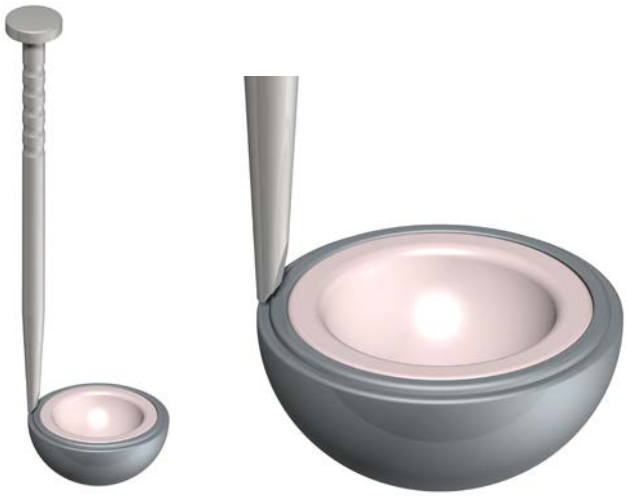
If an inlay replacement is required, screw in a screw in the bottom of the PE-Inlay to be replaced until the PE-Inlay detaches itself from the outer cup.



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

6.1 Implants

Compatibility overview: BSC Macro Cups with PE, Xonit X-PE, Xonit-E X-PE und Ceramic Inlays:

BSC Macro Cup closed, Ref.No. 600.xx.xx / 620.xx.xx Ti/HA
BSC Macro Cup 3 holes, Ref.No. 601.xx.xx / 621.xx.xx Ti/HA)
BSC Macro Cup 3 holes, Ref.No. 602.xx.xx / 622.xx.xx Ti/HA, closed with Coverscrew M8 and Cover M10 (optional)
BSC Macro Cup Multihole, Ref.No. 607.xx.xx / 627.xx.xx Ti/HA

PE Inlay standard, Ref.No. 400/410.xx.xx / dysplasia 401/411.xx.xx
Xonit X-PE Inlay standard, Ref.No. 420.xx.xx / dysplasia 421.xx.xx
Xonit-E X-PE Inlay, Ref.No. 430.xx.xx standard / dysplasia 431.xx.xx
Ceramic Inlay BIOLOX®delta, Ref.No. 317.xx.xx

Cup Ø mm outside	BSC Macro Cup Ref. No.	standard / dysplasiea Ø 28 mm	standard / dysplasiea Ø 32 mm	standard / dysplasiea Ø 36 mm	standard / dysplasiea Ø 40 mm
46	600./601./602./607.39.46	400.28.39 / 401.28.39 420.28.39 / 421.28.39 430.28.39 / 431.28.39	420.32.39 / ----- 430.32.39 / ----- 317.32.39	----------	----------
46	620./621./622./627.39.46 Ti/HA				
48	600./601./602./607.39.48				
48	620./621./622./627.39.48 Ti/HA				
50	600./601./602./607.44.50	400.28.44 / 401.28.44	410.32.44 / 411.32.44 420.32.44 / 421.32.44 430.32.44 / 431.32.44	420.36.44 / ----- 430.36.44 / ----- 317.36.44	----------
50	620./621./622./627.44.50 Ti/HA				
52	600./601./602./607.44.52				
52	620./621./622./627.44.52 Ti/HA				
54	600./601./602./607.48.54	400.28.48 / 401.28.48	410.32.48 / 411.32.48	420.36.48 / 421.36.48 430.36.48 / 431.36.48 317.36.48	420.40.48 / ----- 430.40.48 / ----- 317.40.48
54	620./621./622./627.48.54 Ti/HA				
56	600./601./602./607.48.56				
56	620./621./622./627.48.56 Ti/HA				
58	600./601./602./607.52.58	400.28.52 / 401.28.52	410.32.52 / 411.32.52	420.36.52 / 421.36.52 430.36.52 / 431.36.52 317.36.52	420.40.52 / ----- 430.40.52 / ----- 317.40.52
58	620./621./622./627.52.58 Ti/HA				
60	600./601./602./607.52.60				
60	620./621./622./627.52.60 Ti/HA				
62	600./601./602./607.52.62				
62	620./621./622./627.52.62 Ti/HA				
64	600./601./602./607.52.64				
64	620./621./622./627.52.64 Ti/HA				
66	600./601./602./607.52.66				
66	620./621./622./627.52.66 Ti/HA				

6. Ordering information

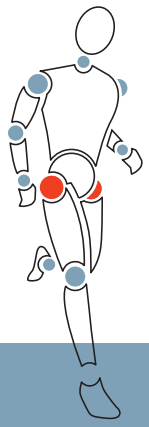
6.2 Implants

Compatibility overview: BSC Macro Cup Clusterhole with PE, Xonit X-PE, Xonit-E X-PE and Ceramic Inlays:

BSC Macro Cup Clusterhole, Ref. No. 605.xx.xx / 625.xx.xx Ti/HA

PE Inlay standard, Ref. No. 400/410.xx.xx / dysplasia 401/411.xx.xx
Xonit X-PE Inlay standard, Ref. No. 420/450.xx.xx / dysplasia 421.xx.xx
Xonit-E X-PE Inlay, Ref. No. 430/440.xx.xx standard / dysplasia 431.xx.xx
Ceramic Inlay BIOLOX®delta, Ref. No. 317.xx.xx

Cup Ø mm outside	BSC Macro Cup Clusterhole Ref. No.	standard / dysplasia Ø 28 mm	standard / dysplasia Ø 32 mm	standard / dysplasia Ø 36 mm	standard / dysplasia Ø 40 mm
50	605.35.50	450.28.35 / ..... 440.28.35 /..... 317.28.35	----------	----------	----------
50	625.35.50 Ti/HA				
52	605.35.52				
52	625.35.52 Ti/HA				
54	605.39.54	400.28.39 / 401.28.39 420.28.39 / 421.28.39 430.28.39 / 431.28.39	420.32.39 / ----- 430.32.39 / ----- 317.32.39	----------	----------
54	625.39.54 Ti/HA				
56	605.39.56				
56	625.39.56 Ti/HA				
58	605.39.58				
58	6250.39.58 Ti/HA				
60	605.44.60	400.28.44 / 401.28.44	410.32.44 / 411.32.44 420.32.44 / 421.32.44 430.32.44 / 431.32.44	420.36.44 / ----- 430.36.44 / ----- 317.36.44	----------
60	625.44.60 Ti/HA				
62	605.44.62				
62	625.44.62 Ti/HA				
64	605.48.64	400.28.48 / 401.28.48	410.32.48 / 411.32.48	420.36.48 / 421.36.48 430.36.48 / 431.36.48 317.36.48	420.40.48 / ----- 430.40.48 / ----- 317.40.48
64	625.48.64 Ti/HA				
68	605.48.66				
68	625.48.66 Ti/HA				

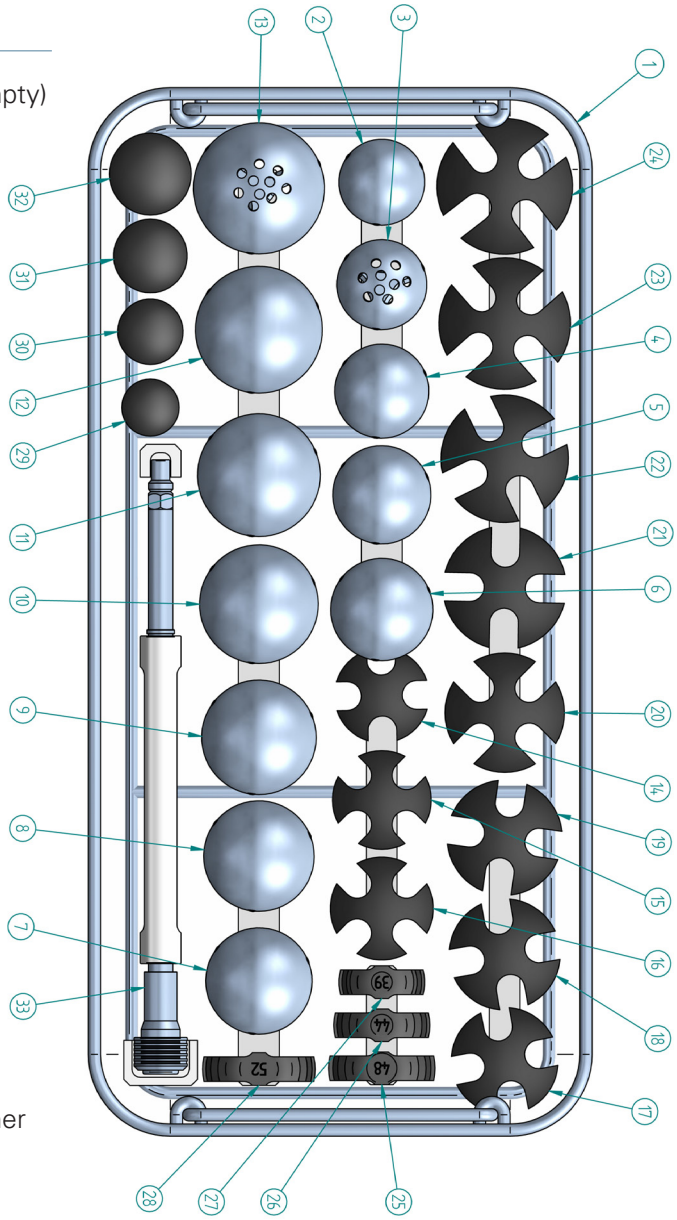


Instruments - Sterility

The instruments are not sterile when they are delivered. Before use, they must be reprocessed and sterilized according to Stemcup's Instrument-Leaflet. The instruction leaflet for instruments „Recommendation Care - Cleaning - Maintenance - Sterilization" is available upon request, resp. is inclosed in the instrument set.
Instrument manufacturers and distributors accept no responsibility for sterilization of products by the customer. The applicable legal regulations for the reprocessing of medical devices in your country must be observed. In countries where stricter requirements apply, these must be adhered to.

6.3 BSC Cup - Instruments Tray 1

Pos.	Ref.No.	Description
1.	60.301.801.01-90	Instrumentset 1 for BSC-cup (empty)
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.	65.311.46	Test-cup size 46*
15.	65.311.48	Test-cup size 48
16.	65.311.50	Test-cup size 50
17.	65.311.52	Test-cup size 52
18.	65.311.54	Test-cup size 54
19.	65.311.56	Test-cup size 56
20.	65.311.58	Test-cup size 58
21.	65.311.60	Test-cup size 60
22.	65.311.62	Test-cup size 62
23.	65.311.64	Test-cup size 64
24.	65.311.66	Test-cup size 66
25.	65.331.37	Controll gauge size 48 for BSC-Cup
26.	65.331.36	Controll gauge size 44 for BSC-Cup
27.	65.331.35	Controll gauge size 39 for BSC-Cup
28.	65.331.38	Controll gauge size 52 for BSC-Cup
29.	60.1041	Impactor attachment for Inlay 28
30.	60.1042	Impactor attachment for Inlay 32
31.	60.1043	Impactor attachment for Inlay 36
32.	60.1053	Impactor attachment for Inlay 40
33.	65.301.14	Guiding shaft with quick release fastener

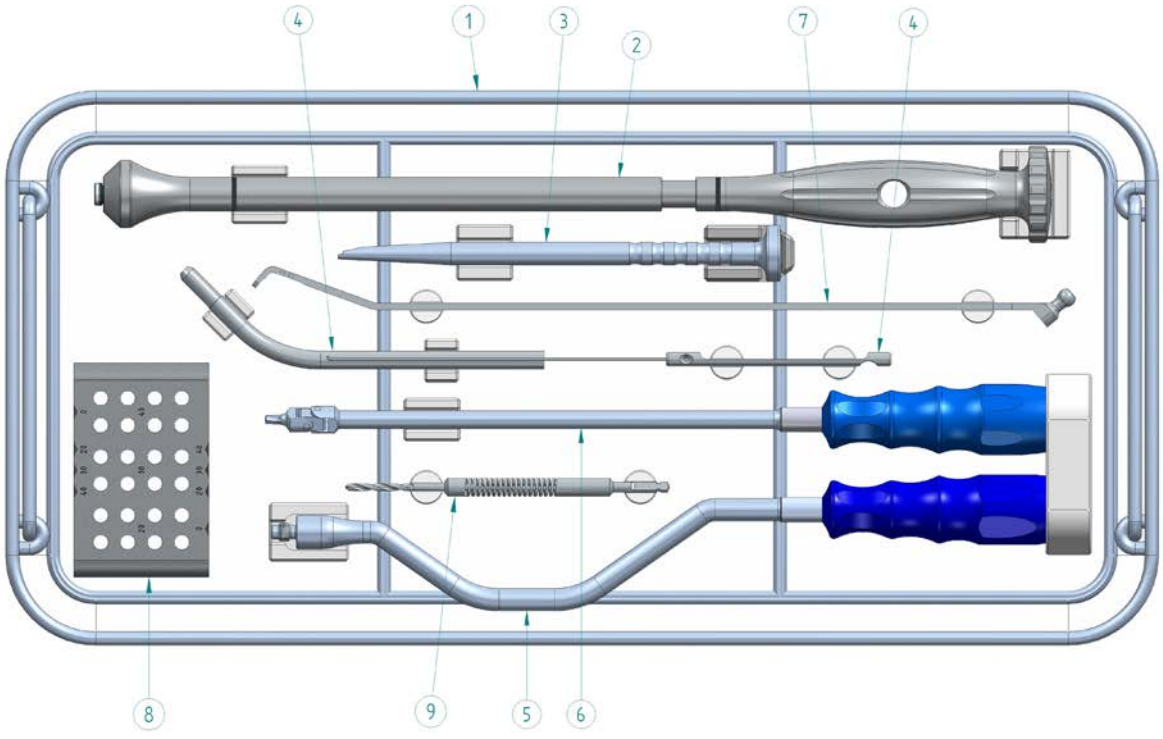


*Alternatively can be used Metall Test-cup
Ref.No.: 60.00.46 - 60.00.66

6. Ordering information

6.4 BSC Macro Cup - Instruments Tray 2

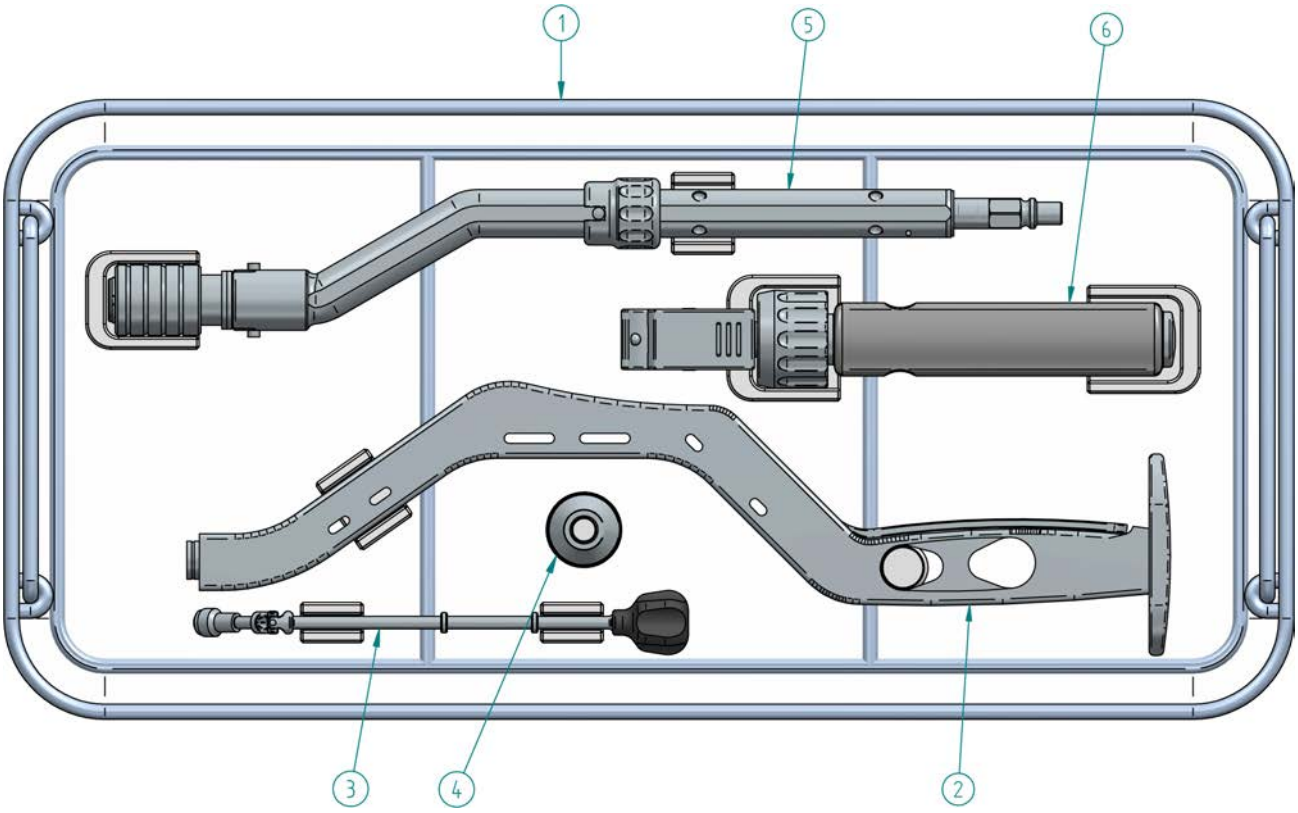
Pos.	Ref.No.	Description
1.	65.600.801.02-90	Instrumentset 2 for BSC Macro cup (empty)
2.	60.1079	Impactor BSC Macro straight
3.	60.1051	Ceramic-Inlay extractor
4.	367-115	Screw measuring device bent 2-piece
5.	60.1018	Pusher curved
6.	65.331.43	Universal joint screw driver
7.	65.331.41	Fixation for drill guide and screw holder
8.	65.301-02-05	Holder for titanium screws
9.	367-1316	Flexible drill short 110 mm



6. Ordering information

6.5 BSC Macro Cup - Instruments Tray 3

Pos.	Ref.No.	Description
1.	65.600.801.03-90	Instrumentset 3 for BSC Macro cup (empty)
2.	60.1076	Offset Cup Impactor
3.	60.1076-01	Locking screw M10x1
4.	60.1076-10	Impactor Nose
5.	60.1062	Offset guidingshaft synthes-ao-connection
6.	60.1062 handle	Handle for 60.1062



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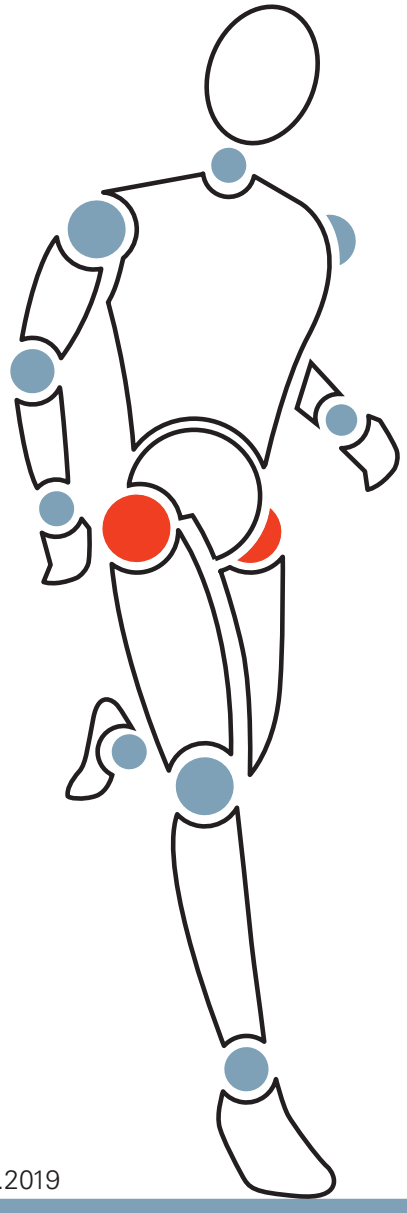

We are there when you need us:

Switzerland Headquarters
Stemcup Medical Products AG
Aargauerstrasse 180
CH- 8048 Zürich
Tel. +41 (0)43 311 85 00
Fax. +41 (0)43 311 85 09
info@stemcup.ch
www.stemcup.ch

Germany
Stemcup Medical Products GmbH
Wallbrunnstrasse 24
D-79539 Lörrach
Tel. +49 (0) 7621 162 00 49
Fax. +49 (0) 7621 161 97 78
info@stemcup.de
www.stemcup.de

Austria
Stemcup Medical Products Austria GmbH
Schwindgasse 20/1/4
A-1040 Wien
Tel. +43 (0) 1 890 40 53
Fax. +43 (0) 1 890 40 54
info@stemcup.at
www.stemcup.at

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