swiss design
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Bipolar Ballhead

Surgical Technique

stemcup

Medical products in motion

- Nota Bene -

Nota Bene
The technique description herein is made available to the healthcare professional to illustrate the authors' suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the needs of the patient.

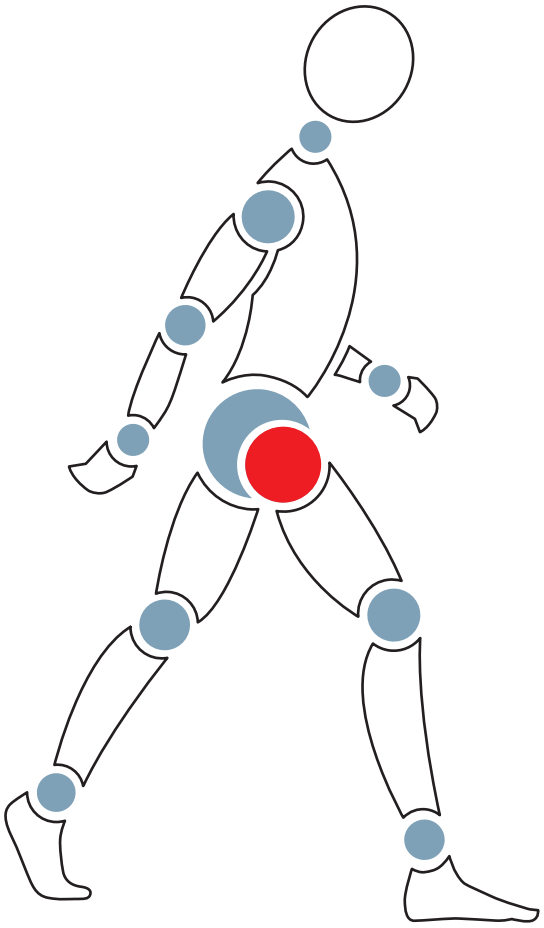

Table of contents

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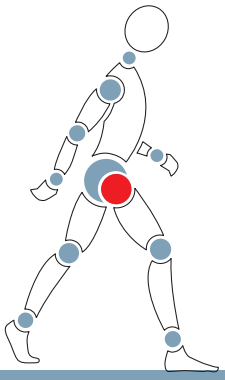


1. Introduction

1.1 Bipolar ballhead with retaining ring

The Bipolar ballhead has the function of a femoral head replacement in connection with hip stem prostheses. The Bipolar ballhead is particularly suitable for the treatment of femoral neck fractures and is suitable as a direct sliding partner with the acetabulum.

The principle of the Bipolar ballhead with different centers of rotation for the head and the outer shell has been established for years as the standard for a hemiprosthesis. High freedom of rotation and low relative movements between the acetabulum and the outer shell are the main features of this system. Different centers of rotation of the femoral head and outer shell of the Bipolar ballhead lead to self-centering of the implant. The acetabular cartilage is protected in the best possible way due to the large contact area and the highly polished metal surface of the Bipolar ballhead. The removable, correctly placed locking ring connects the Bipolar ballhead to the femoral head in a luxation-proof manner.

The Bipolar ballheads all have a positive eccentricity, i.e. a displacement of the femoral head center of rotation in the proximal direction on the line of symmetry opposite the center of rotation of the Bipolar ballhead Shell.
This displacement results in a torque due to the forces F and R that are always acting. This torque reinforces the tendency of the bipolar ball head to always align itself in a stable position. This so-called self-centering effect achieves an optimized load distribution.

Abb.01: Bipolar ballhead with retaining ring

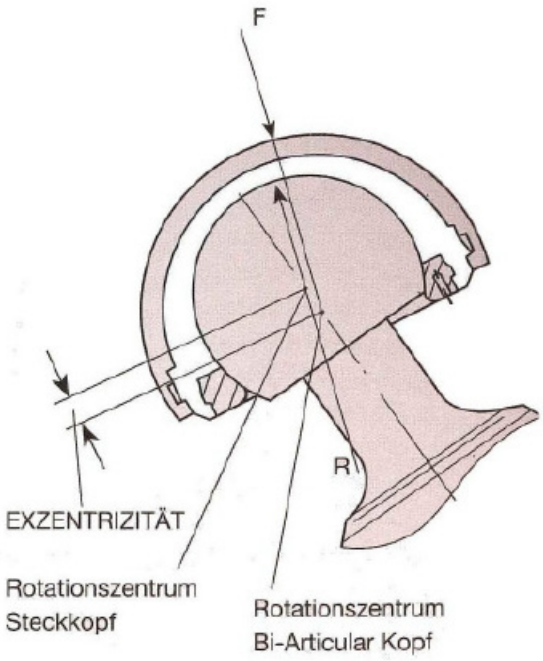


Abb.02: Bipolar ballhead eccentricity

2. System description

2.1 Prosthesisdesign

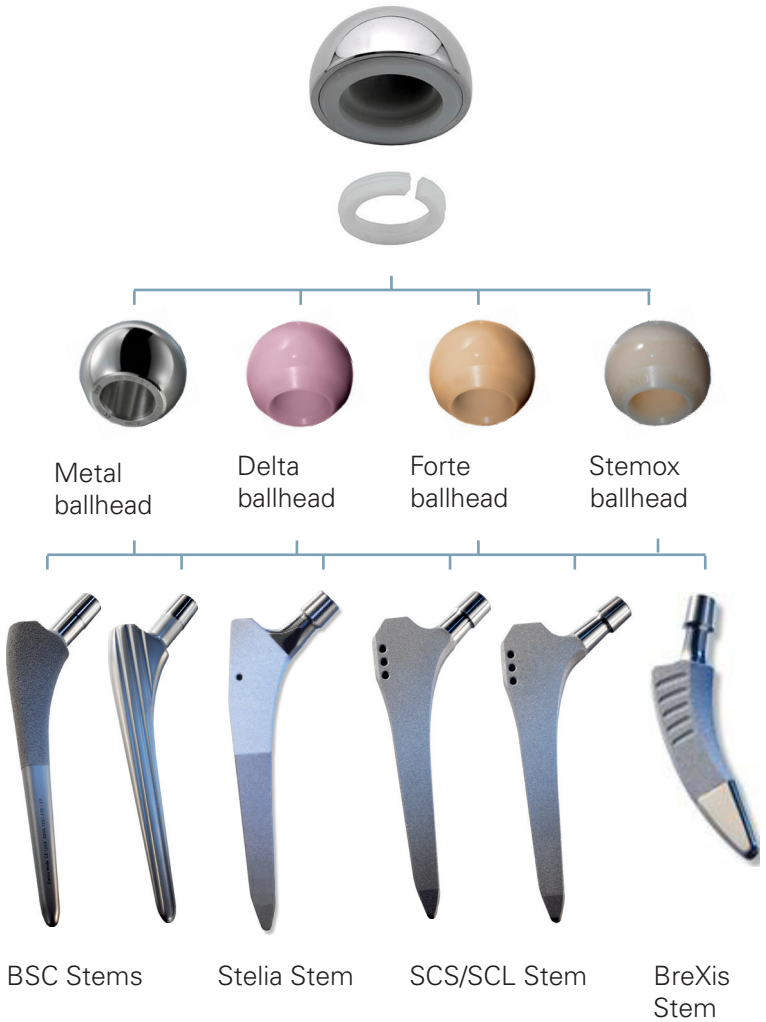
The Bipolar ballhead consists of an outer shell made of stainless CrNi steel according to ISO 5832-1 or of CoCrMo according to ISO 5832-4 and an insert with locking ring made of polyethylene (UHMWPE) according to ISO 5834-2. 23 sizes (43-65 mm, in 1-mm increments) allow optimal restoration of anatomical relationships.

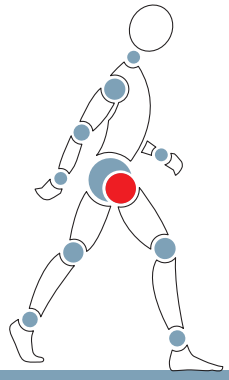
In addition, there are 4 Bipolar ballheads in smaller sizes (39-42 m), which are combined with a 22 mm metal ball head. The variable combination options consist of ball heads with up to five neck lengths (S, M, L, XL and XXL).
The acetabulum is spared, as the main articulation takes place between the prosthesis head and the Bipolar ball head. In addition, the highly polished metal surface minimizes friction between implant and acetabulum.
The self-centering effect of the Bipolar ballheads promotes the neutral position of the implant. The PE insert, which is firmly anchored in the metal shell, prevents micromovements and polyethylene abrasion. In addition, the locking ring is optimal protection against the risk of dislocation.

2.2 Possible combinations

The Bipolar ballheads and the ballheads can be combined with all Stemcup stems.

Abb. 03: Possible combinations





3. Indications / Contraindications / E-IFU

3.1 Indications

- Non-inflammatory degenerative joint disease (NIDJD) e.g. osteoarthritis (arthrosis/primary, secondary, dysplasia coxarthrosis etc.)
- Inflammatory joint disease (IJD) e.g. rheumatoid 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 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.

3.2 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

3.3 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.

4. Preoperative Planning

X-ray templates with 15% magnification are available for preoperative size selection of the prosthesis.

Figure 04 shows a size 42 Bipolar ball head and Figure 05 a preoperative planning of a BreXis short stem.
The information given in the surgical technique are recommendations and hints, the detailed implementation or the possibility of implementation depends on the individual skills as well as experience of the user.

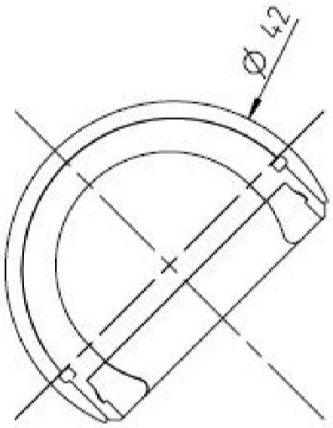


Abb.04: Image from X-ray template for size 42

Access to the hip joint
Any access to the hip joint deemed appropriate by the surgeon is possible. The surgeon must have a good view of the anatomical structures so that correct work with the instruments is not impeded.

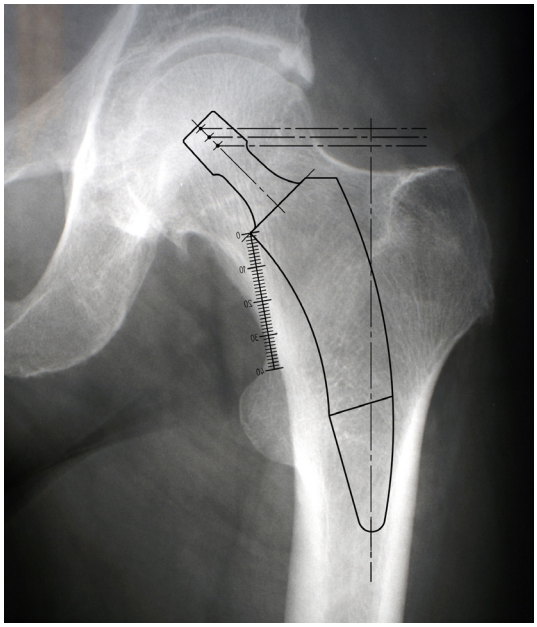
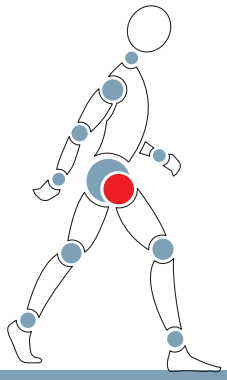


Abb.05: X-ray image with BreXis short stem



5. Surgical Technique

5.1 Resection of the femoral head

After opening the joint capsule and dislocating the femoral head from the acetabulum, resect it in the same manner as the preoperative planning of the hip stem.

5.2 Preparation of the femur

The femur is prepared according to the surgical instructions of the corresponding stem, which is inserted.
It is assumed that the procedure is performed according to the instructions of the corresponding stem product used and that the femoral side has progressed to a point where the use of a ball head can be performed without further preparatory work.

5.3 Ball head neck length determination

A manipulation head Abb.06 (diameter matching the inner diameter of the selected bipolar ball head) is placed on an already firmly implanted prosthesis stem in order to then perform a trial position with the predetermined bipolar ball head size. Both range of motion and leg length must be checked. This procedure may have to be repeated until the correct femoral head length is found.

Abb.06 implanted stem

5.4 Trial ballheads

For trial positioning, trial ballheads (Abb.07) are available in diameters ø22 mm, and ø28 mm, in neck lengths S, M, L, XL and XXL for 28 mm ballheads and M and L for 22 mm ballheads.

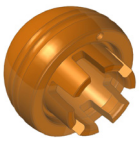


Abb.07 Trial ballhead with Ø 22mm and Ø 28mm

5. Surgical Technique

5.5 Determining the implant size

The correct Bipolar ballhead size (39/22-42/22 or 43/28-65/28) can be determined in the acetabulum with the Trial Bipolar ballhead (Fig.08).

The size of the first trial head matches the diameter of the natural resected femoral head. If this does not fit, the next larger or smaller trial head must be taken until the correct size is found.

Abb.08 Bipolar Trial ballhead

5.6 Implantation of the ball head with locking ring

When size and neck length are found to be correct, after removing the manipulation head, the locking ring is passed over the stem taper and the final ball head is placed under slight pressure and rotational movement (Fig.09).

The ball head is finally fixed in place using the ball head impactor (Fig.10) and the hammer (never use the hammer without the head impactor).

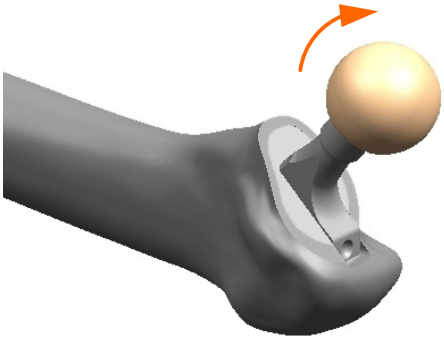


Abb.09 Mounting the ballhead on the stem

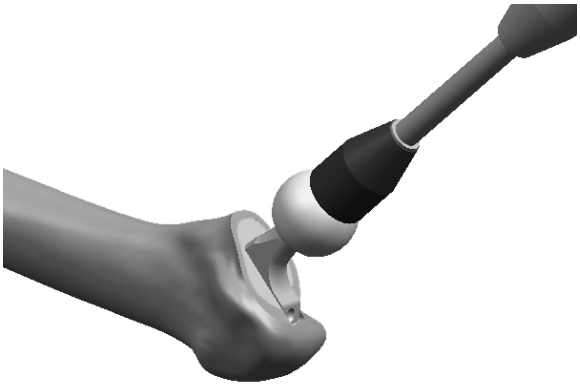
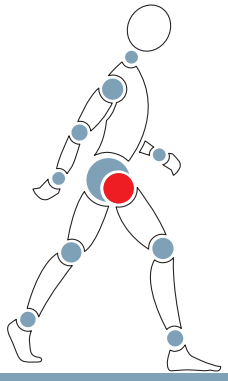


Abb.10 Fixation of the ballhead with the impactor



5. Surgical Technique

5.7 Implantation of the Bipolar ballhead

The Bipolar ballhead is then placed on the ballhead and the PE retaining ring is firmly engaged in the groove in the Bipolar ballhead with the repositioning forceps.

Warning:
The ring must be fully engaged and must not protrude!

The free articulations between the Bipolar ballhead and the ballhead as well as between the Bipolar ballhead and the acetabulum must be checked!

Repeat reduction and subsequent wound closure.

The ballhead can now rotate in the PE insert without luxating.

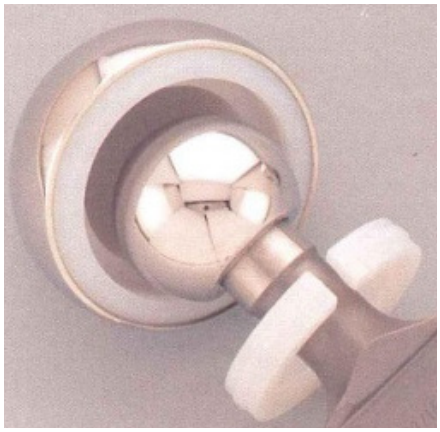
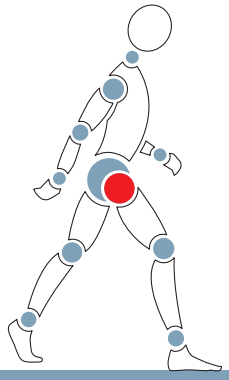


Abb.11: PE retaining ring threaded over the neck of the stem and attached metal ballhead before fixation of the Bipolar ballhead

Abb.12: Bipolar ballhead with PE locking ring fixed with reduction forceps.

5.8 Prosthesis removal

If it is necessary intraoperatively to remove the original prosthesis that has already been inserted, the locking ring is removed first and then the bipolar ball head.



Sterility implants
All implants described in this surgical technique are supplied sterile by the manufacturer. Resterilization is not permitted.

6. Bipolar ballhead implant article overview

6.1 Bipolar ballhead with retaining ring

Material:
Shell made of implant steel CrNi-ISO 5832-1 and/or implant steel CrCoMo-ISO 5834-4 with retaining ring UHMWPE ISO 5834-1+2, inner diameter 22 and 28mm

Description Size (ID/OD)	Ballhead CrNi REF	Ballhead CrCoMo REF
Bipolar ballhead, 39/22 mm	138.22.39	139.22.39
Bipolar ballhead, 40/22 mm	138.22.40	139.22.40
Bipolar ballhead, 41/22 mm	138.22.41	139.22.41
Bipolar ballhead, 42/22 mm	138.22.42	139.22.42
Bipolar ballhead, 43/28 mm	138.28.43	139.28.43
Bipolar ballhead, 44/28 mm	138.28.44	139.28.44
Bipolar ballhead, 45/28 mm	138.28.45	139.28.45
Bipolar ballhead, 46/28 mm	138.28.46	139.28.46
Bipolar ballhead, 47/28 mm	138.28.47	139.28.47
Bipolar ballhead, 48/28 mm	138.28.48	139.28.48
Bipolar ballhead, 49/28 mm	138.28.49	139.28.49
Bipolar ballhead, 50/28 mm	138.28.50	139.28.50
Bipolar ballhead, 51/28 mm	138.28.51	139.28.51
Bipolar ballhead, 52/28 mm	138.28.52	139.28.52
Bipolar ballhead, 53/28 mm	138.28.53	139.28.53
Bipolar ballhead, 54/28 mm	138.28.54	139.28.54
Bipolar ballhead, 55/28 mm	138.28.55	139.28.55
Bipolar ballhead, 56/28 mm	138.28.56	139.28.56
Bipolar ballhead, 57/28 mm	138.28.57	139.28.57
Bipolar ballhead, 58/28 mm	138.28.58	139.28.58
Bipolar ballhead, 59/28 mm	138.28.59	139.28.59
Bipolar ballhead, 60/28 mm	138.28.60	139.28.60
Bipolar ballhead, 61/28 mm	138.28.61	139.28.61
Bipolar ballhead, 62/28 mm	138.28.62	139.28.62
Bipolar ballhead, 63/28 mm	138.28.63	139.28.63
Bipolar ballhead, 64/28 mm	138.28.64	139.28.64
Bipolar ballhead, 65/28 mm	138.28.65	139.28.65

Abb.13: Bipolar ballhead with retaining ring

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.

7. Bipolar ballhead Instruments Article overview

7.1 Bipolar Trial ballheads for determining the Bipolar ballhead size

To ensure flawless function and implantation, only original instruments may be used. The simple and functional instrument set supports a controllable and safe preparation and insertion of the implant at any time.
Bipolar Trial ballhead: Material Propylux

REF	Description
60.138.39	Bipolar Trial ballhead 39/22 mm
60.138.40	Bipolar Trial ballhead 40/22 mm
60.138.41	Bipolar Trial ballhead 41/22 mm
60.138.42	Bipolar Trial ballhead 42/22 mm
60.138.43	Bipolar Trial ballhead 43/28 mm
60.138.44	Bipolar Trial ballhead 44/28 mm
60.138.45	Bipolar Trial ballhead 45/28 mm
60.138.46	Bipolar Trial ballhead 46/28 mm
60.138.47	Bipolar Trial ballhead 47/28 mm
60.138.48	Bipolar Trial ballhead 48/28 mm
60.138.49	Bipolar Trial ballhead 49/28 mm
60.138.50	Bipolar Trial ballhead 50/28 mm
60.138.51	Bipolar Trial ballhead 51/28 mm
60.138.52	Bipolar Trial ballhead 52/28 mm
60.138.53	Bipolar Trial ballhead 53/28 mm

REF	Description
60.138.54	Bipolar Trial ballhead 54/28 mm
60.138.55	Bipolar Trial ballhead 55/28 mm
60.138.56	Bipolar Trial ballhead 56/28 mm
60.138.57	Bipolar Trial ballhead 57/28 mm
60.138.58	Bipolar Trial ballhead 58/28 mm
60.138.59	Bipolar Trial ballhead 59/28 mm
60.138.60	Bipolar Trial ballhead 60/28 mm
60.138.61	Bipolar Trial ballhead 61/28 mm
60.138.62	Bipolar Trial ballhead 62/28 mm
60.138.63	Bipolar Trial ballhead 63/28 mm
60.138.64	Bipolar Trial ballhead 64/28 mm
60.138.65	Bipolar Trial ballhead 65/28 mm
60.138.00	Reduction forceps
60.138.01	Bipolar inserter straight
60.138.02	Bipolar inserter curved

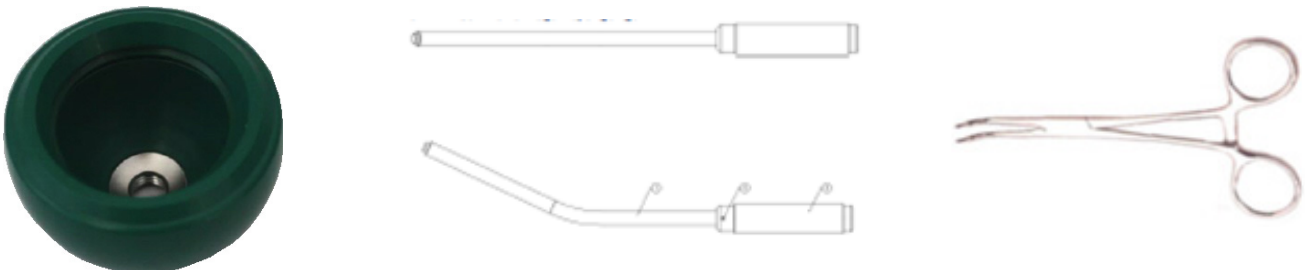
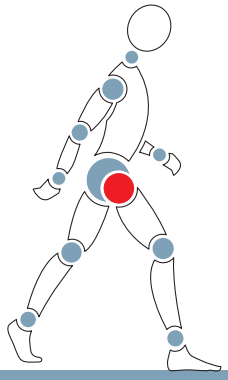


Abb.14: Bipolar Trial ballhead / Insertion Instrument straight / curved / Reduction Forceps



8. Ball heads - Article overview of implants

8.1 Ballheads Metal

Material: Metal CoCrMo - ISO 5832-12

REF	Description
177.02.22	Ballhead CoCrMo ø22mm M
177.03.22	Ballhead CoCrMo ø22mm L
188.01.28	Ballhead CoCrMo ø28mm S
188.02.28	Ballhead CoCrMo ø28mm M
188.03.28	Ballhead CoCrMo ø28mm L
188.04.28	Ballhead CoCrMo ø28mm XL
188.05.28	Ballhead CoCrMo ø28mm XXL

Abb.15: Metal Ballhead

Material: Metal CrNi - ISO 5832-9

REF	Description
197.02.28	Ballhead Metal ø28mm S
197.01.28	Ballhead Metal ø28mm M
197.03.28	Ballhead Metal ø28mm L
197.04.28	Ballhead Metal ø28mm XL
197.05.28	Ballhead Metal ø28mm XXL

8.2 Ceramic ballheads

Material: Ceramic BIOLOX®delta Al2O3/ZrO2 according ISO 6474-2

REF	Description
179.01.28	Ballhead Ceramic Biolox Delta ø28 S
179.02.28	Ballhead Ceramic Biolox Delta ø28 M
179.03.28	Ballhead Ceramic Biolox Delta ø28 L

Abb.16 Ceramic ballhead BIOLOX®delta

Material: Ceramic Stemox: Al2O3 according ISO 6474-1

REF	Description
184.01.28	Ballhead Ceramic Stemox ø28 S
184.02.28	Ballhead Ceramic Stemox ø28 M
184.03.28	Ballhead Ceramic Stemox ø28 L

Abb.17: Ceramic ballhead Stemox

9. Trial ballheads - instruments article overview

9.1 Trial ballheads

The trial ballhead heads are included in the respective stem instrument sets.

Trial ballheads Material: Propylux

REF	Description
60.22.12	Trial ballhead Ø 22mm M
60.22.13	Trial ballhead Ø 22mm L
60.28.11	Trial ballhead Ø 28mm S
60.28.12	Trial ballhead Ø 28mm M
60.28.13	Trial ballhead Ø 28mm L
60.28.14	Trial ballhead Ø 28mm XL
60.28.15	Trial ballhead Ø 28mm XXL

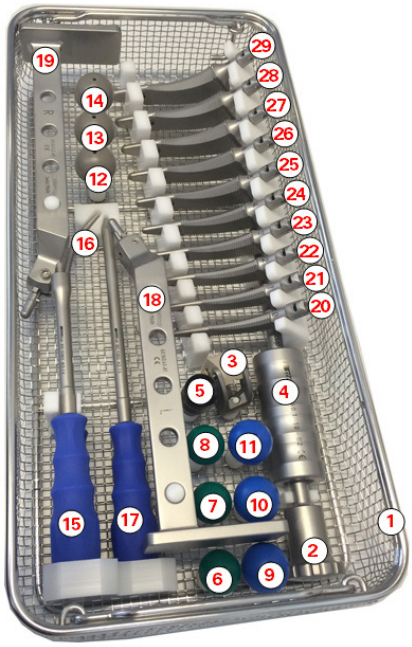
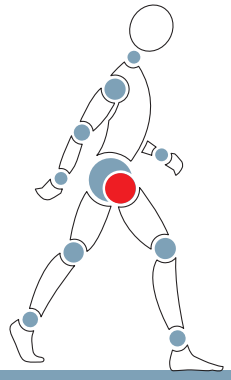


Abb.18: as an example a BreXis instrument set with Trial ballheads.



10. Notes

30 JAHRE

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swiss made
swiss quality

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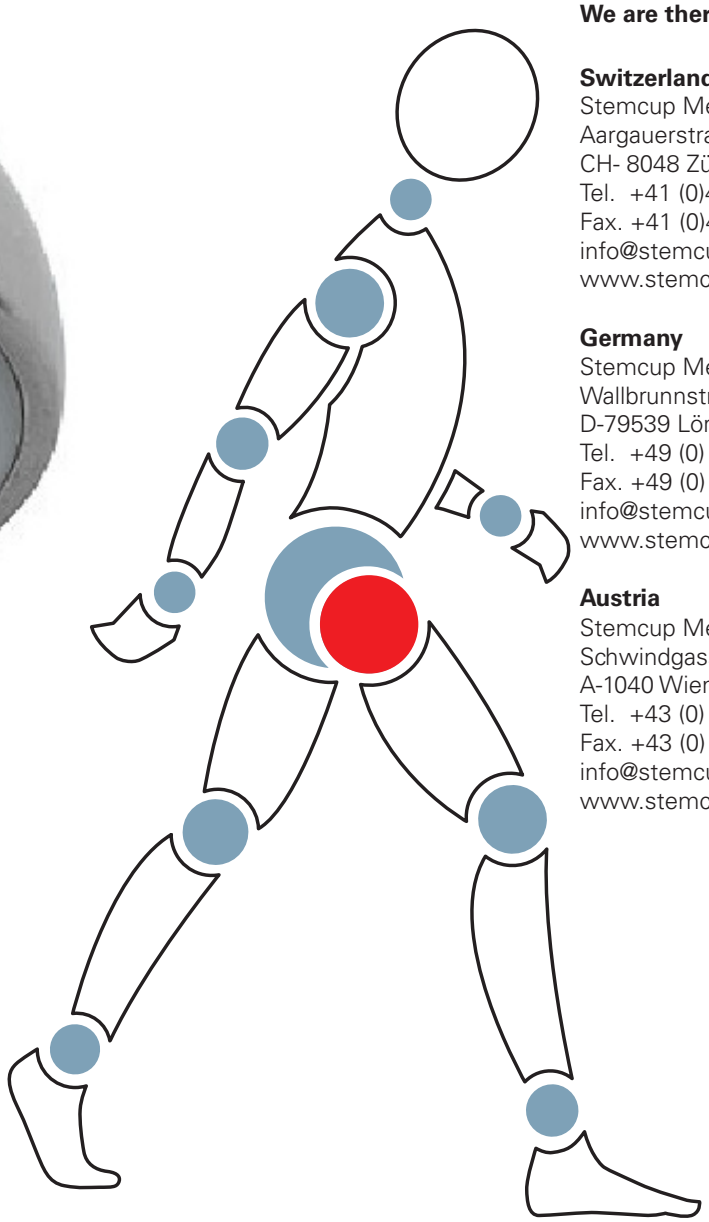

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