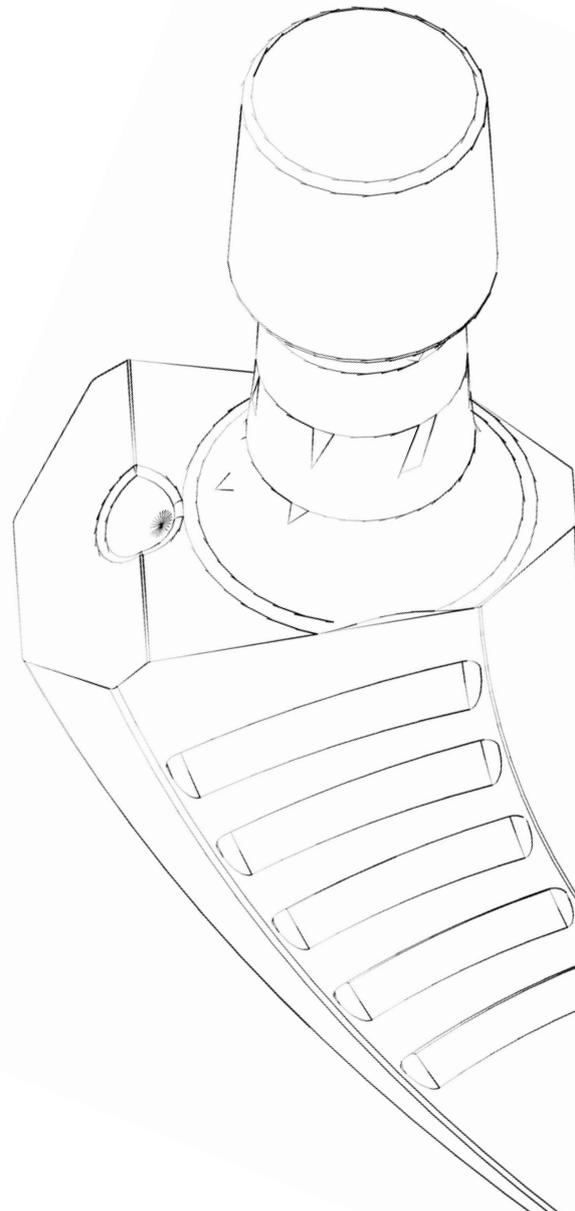
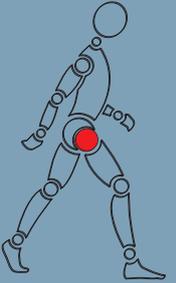


# BreXis Short Stem

## Surgical Technique



 swiss design  
swiss made  
swiss quality

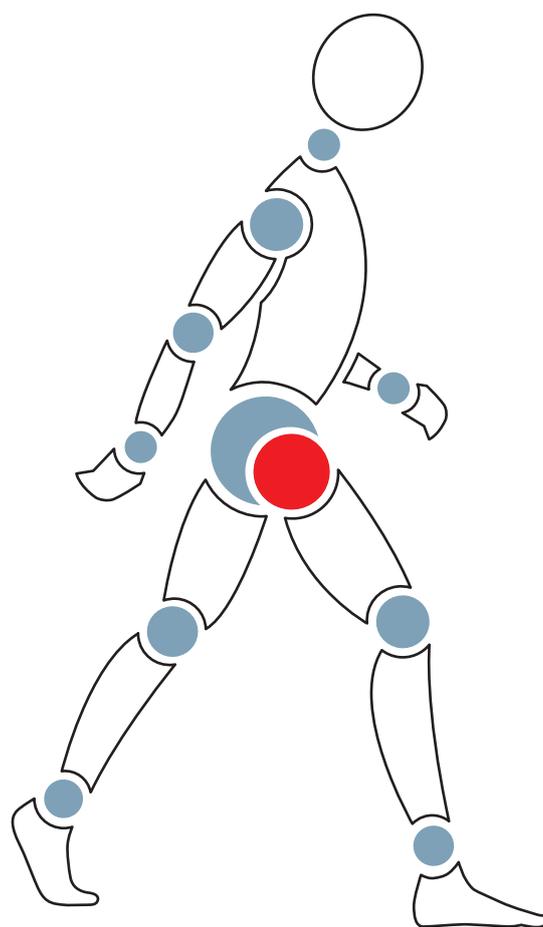
**stemcup**

Medical products in motion

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### 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.

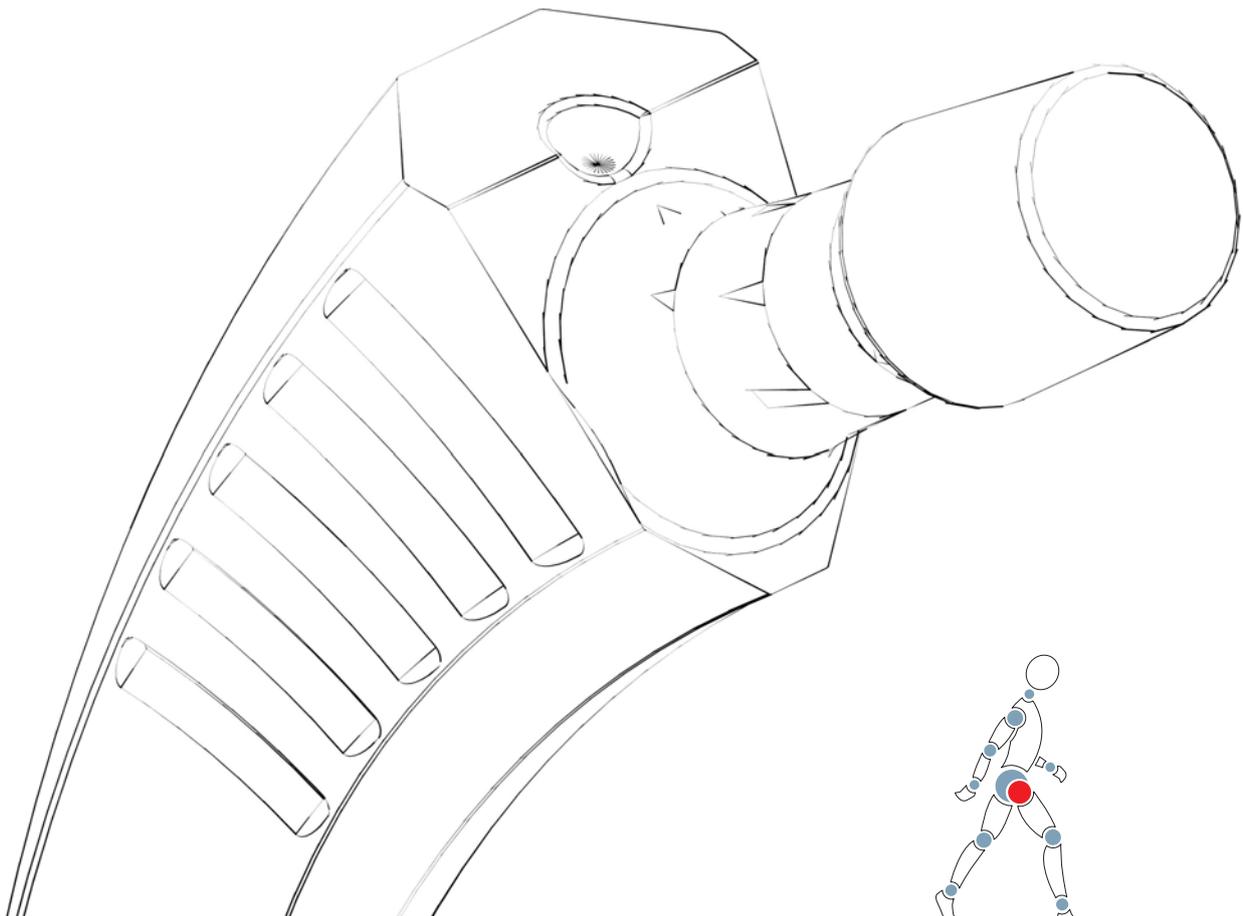


## 1. Introduction

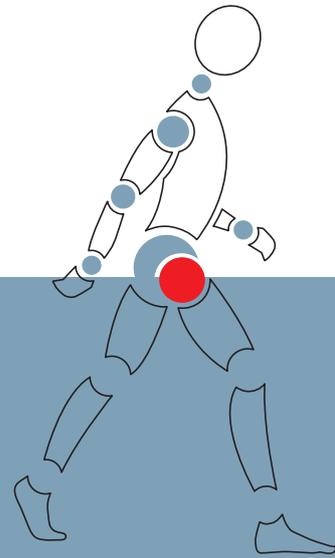
The BreXis Short-Stem was developed to create a system with metaphyseal anchorage and load distribution. The implant requires only minimal bone resection. The cancellous bone around the metaphysis and the greater trochanter are retained to ensure load distribution and transfer. This upholds the principle of the "second line of defence" for this prosthesis concept.

Ten sizes designed to complement each other and a clearly arranged set of instruments make it easier for the surgeon to intraoperatively determine and select the suitable implant.

The BreXis Short-Stem has been developed based on clinical experience of various "Short-Stem prostheses" and is the third generation of this type of prosthesis.



## 2. Development / Concept



The concept of the BreXis Short-Stem is to have as long as possible an attachment in the region of the calcar in order to ensure optimum load transfer and to have a cortical attachment in the distal -lateral side to support and compensate loads in the varus direction.

The materials selected for the BreXis Short-Stem are also state-of-the-art. The implant is made of a proximal osteoconductive coated titanium forged-alloy (ISO 5832-3).

The surface roughness of the titanium plasma coating on one hand increases the surface area and on the other ensures superior primary stability. The additional HA coating allows to accelerate the osseointegration process.

There are a total of 10 sizes available. This allows individual, optimum sizing to be carried out in the preoperative planning stage and implemented intraoperatively. The part of the femoral neck below the taper has been modified to increase the range of motion.



## 3. System description

### 3.1 Prosthesis design

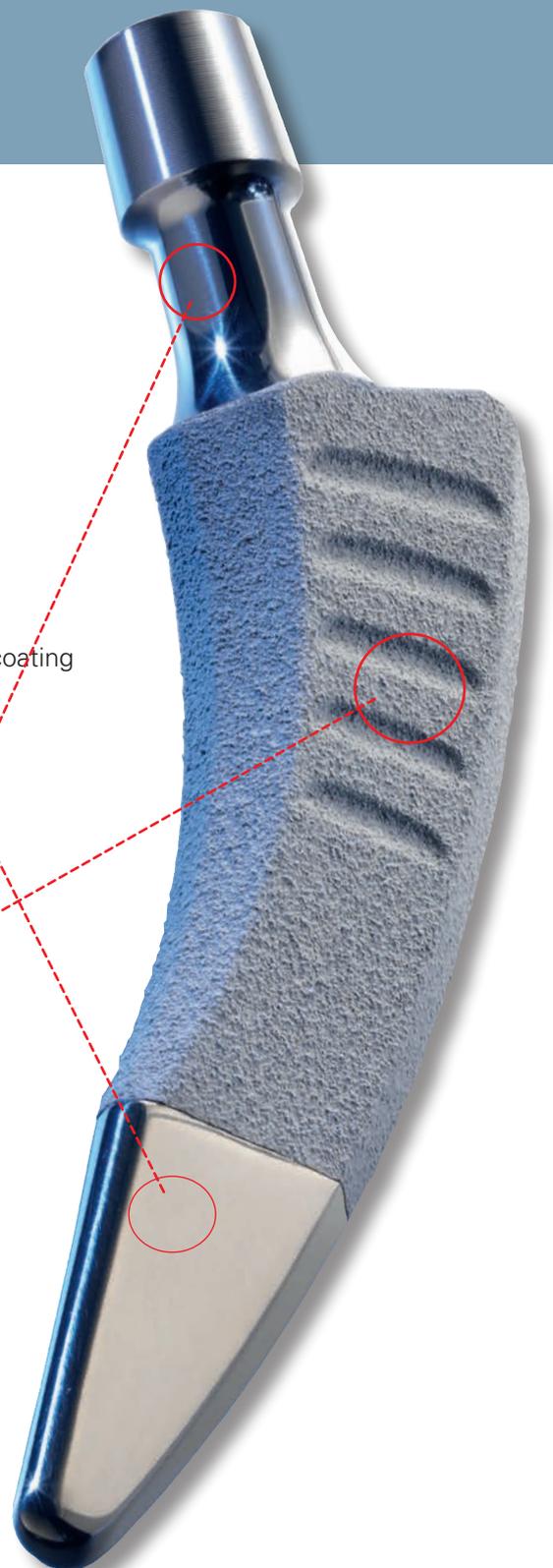
- Sizes: 0-10
- Raw material: Ti6Al4V
- Anchorage: double tapered basic shape
- Rotational stability: trapezoidal cross-section
- Coating: porous titanium-hydroxylapatite coating

#### *Polished is brilliant in use*

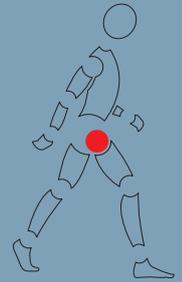
The neck of the prosthesis is polished in order to achieve an even higher durability of the already highly durable titanium-forged alloy. The distal end of the prosthesis is polished as well, therefore avoiding bone ingrowth and minimizing "prosthesis-tip-pain".

#### *Macro structure*

The proximal macro structure increases the contact surface between implant and bone and reduces the risk of subsidence.



## 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, loosening, 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.

**Further circumstances, which require special attention: BreXis Short-Stem**

- Adiposity (obesity) (Body-Mass-Index BMI >30).
- Extreme strains (e.g. through sports or work), especially concerning patients who weigh more than 100 kg.
- Use only spherical heads with size S, M, L or XL.

## 4. Contraindications / E-IFU

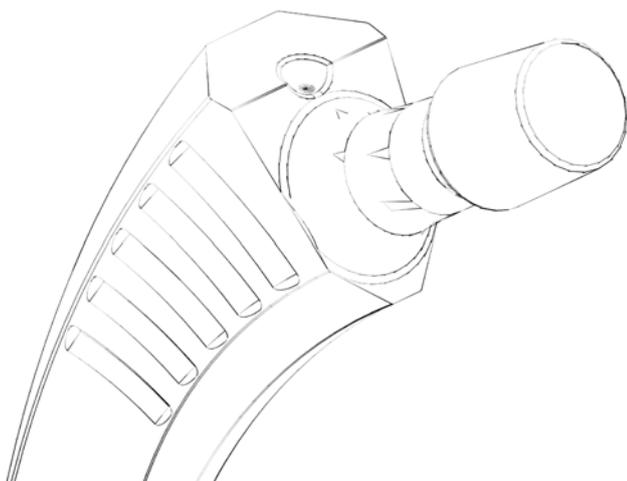
### 4.2 Contraindications

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

#### **Additional Contraindications: BreXis Short-Stem**

- Pronounced coxa valga with a femoral neck angle  $> 145^\circ$
- Pronounced coxa vara with a femoral neck angle  $< 125^\circ$

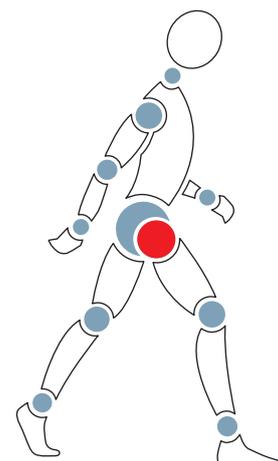


### 4.3 E-IFU

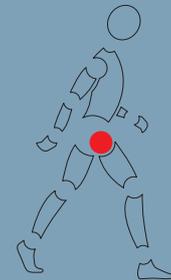
The E-IFU (Instruction for Use) is available online. On the product labels there will be the link to [www.stemcup.com](http://www.stemcup.com). On this website the electronic IFU can be downloaded. You need to enter the IFU Code which is printed on the product label to be forwarded to the page where 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 be 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](mailto:administration@stemcup.ch) or send us a fax on the appropriate fax numbers of Stemcup Switzerland, Germany or Austria.



## 5. Preoperative Planning



X-ray templates with 15% enlargement are available to preoperatively determine the size of the prosthesis. The size and position of the prosthesis are planned using the anterior/posterior and the axial x-ray image (Fig.1).

Depending on the system requirements, attachment is advised in the anterior/posterior region on the calcar femoris, and the lateral corticalis in the region of the tip of the prosthesis.

In the axial x-ray a proximal pressfit in the ventro/dorsal region and support of the tip of the prosthesis in the region of the dorsal femoral cortical bone is achieved.

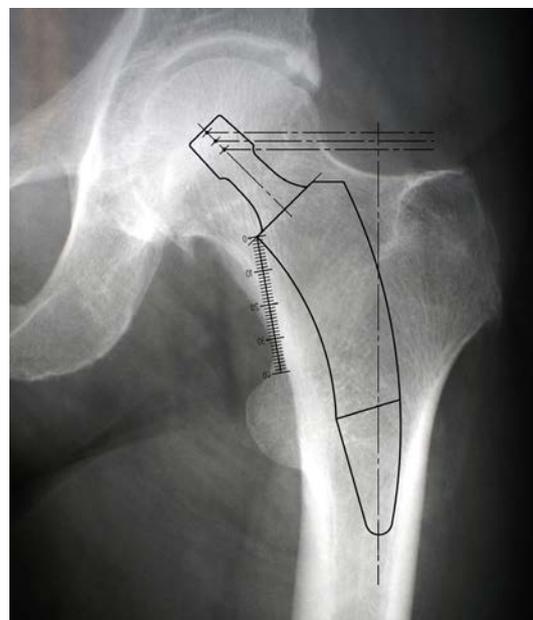


Fig.1: X-ray with BreXis Short-Stem

Fig. 2: Postoperative BreXis Schort Stem in combination with BSC Cup and ceramic Ballhead. 03.12.2014.



## 6. Surgical Technique

### 6.1 Resection of the femoral neck

A maximum amount of bone is preserved during the resection of the femoral neck.

The resection level for the removal of the femoral head is approximately 0.5 to 1.0 cm subcapital, close to a right angle to the femoral neck (Fig. 3).

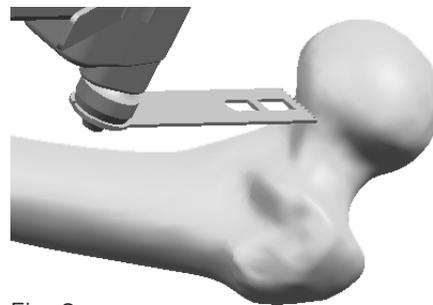


Fig. 3

### 6.2 Preparing the femoral neck

The curved opening rasp is used to prepare the path for the forming rasps (Fig.4). The rasp is inserted with a slight curved motion until the lateral cortical bone is reached approximately at the height of the bottom edge of the lesser trochanter.

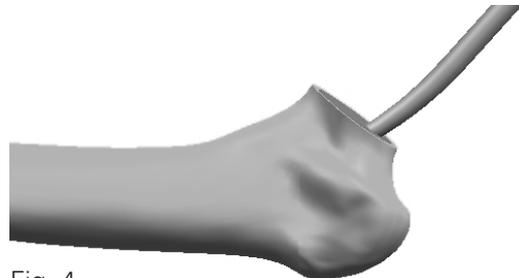


Fig. 4

Rasping is then carried out in stages starting with a size 0 rasp and then with the BreXis- compactor.

### 6.3 Compacting / Raspel

The aim of the preparation is not to rasp out the cancellous bone but to compact it. The preparation is carried out in stages until the planned size is reached and until the compactor is in cortical contact in the load-bearing zones.

The rasps (Fig.6) or compactors (Fig.5) should be used in a slightly curved motion to ensure that there are no gaps between compactor and bone.

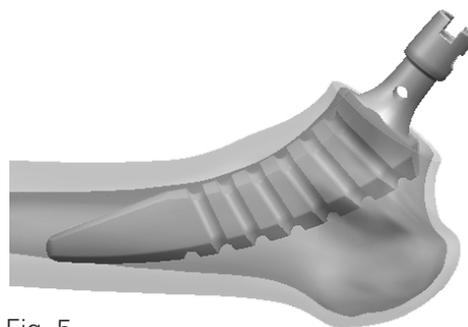
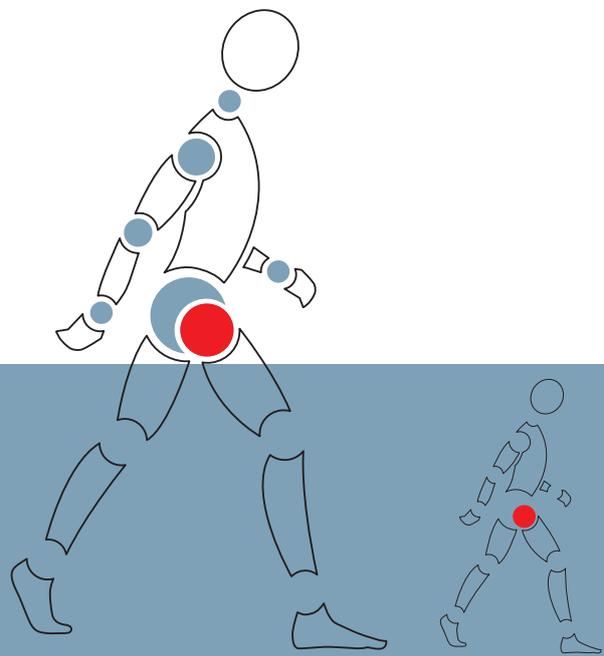


Fig. 5



Fig. 6

## 6. Surgical Technique



### 6.4 Probereposition

Remove the impacting/extraction adapter and fit the trial head of the corresponding neck length on the BreXis-compactor (Fig.7).

Trial heads are available with a diameter of  $\varnothing 28$  mm,  $\varnothing 32$  mm and  $\varnothing 36$  mm each in sizes S, M, L and XL.

Optional diameter  $\varnothing 40$  mm, each in sizes S, M, L and XL are available upon request.

It is advisable to carry out a C-arm check with the compactor in place, to assess that the implant will be adequately seated.



Fig.7

### 6.5 Implanting the stem

Manually insert the original prosthesis of the same size and then impact it to the same depth as the compactor using the inserter (Fig.8).

Carefully clean the taper, fix the head by lightly tapping on the mounted impactor (Fig.9). Alternatively, the femoral head can be fixed by rotating it clockwise.

The wound is sutured in the standard way according to the surgeon's preference.

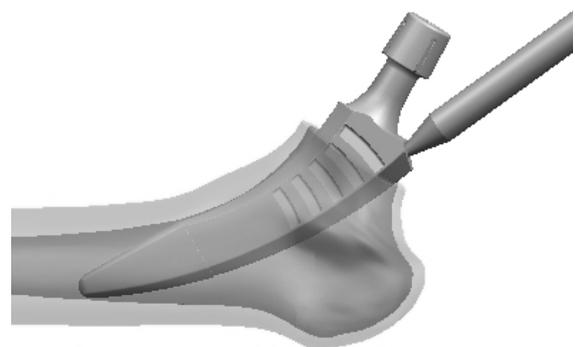


Fig.8

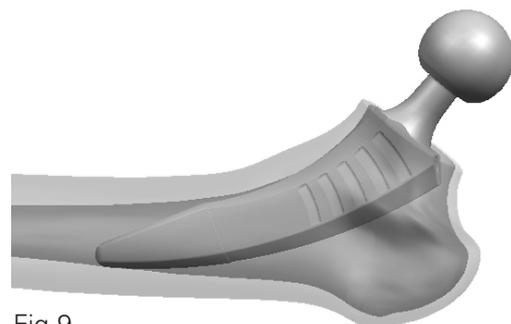
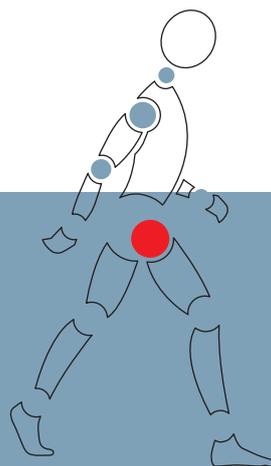


Fig.9

## 6. Surgical Technique



### 6.6 Prosthesis Removal

If it is necessary to intraoperatively remove an original prosthesis, the extraction instrument can be used (Fig.10).

This can be fitted to the taper and connected to the impactor/extraction adapter to remove the implant.

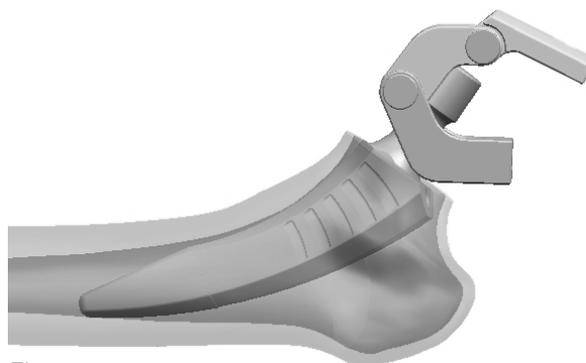


Fig.10

Slide the extraction instrument (Fig.12) over the stem taper (Fig.11) and connect it with the extractor rod (Fig.14) and slide weight extractor (Fig.13). Make sure that the instrument is firmly fixed. Remove the BreXis Short Stem by hammering back with a sliding weight for extractor.

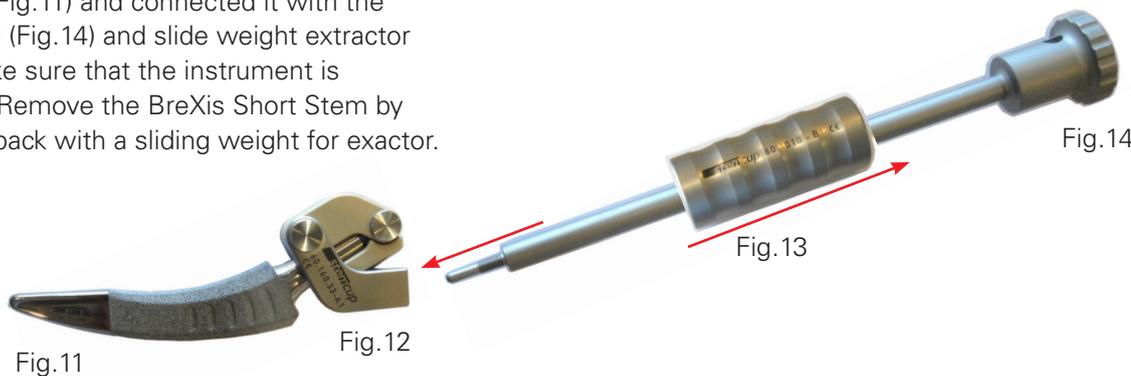


Fig.11

Fig.12

Fig.13

Fig.14

### 6.7 Postoperative Treatment

Postoperatively the leg should be placed in a splint in abduction and neutral rotation. On the second day the drains are removed.

Mobilization with the three-point gait (partial load bearing of 15 to 20 kg) is carried out starting on the first postoperative day for a period of 4–6 weeks. After this period load bearing is increased depending on x-ray findings.

## 7. Ordering Information for Implants

### 7.1 BreXis Short-Stem Implants

**BreXis Short Stem standard, cementless, Ti/HA coated  
Ti6Al4V / ISO 5832-3  
Cone 12/14**

STERILE R

Ref.	Description	Dimensions	Length in mm
160.00.00	BreXis Short Stem, standard	Size 0	85.5
160.00.01	BreXis Short Stem, standard	Size 1	88.9
160.00.02	BreXis Short Stem, standard	Size 2	92.3
160.00.03	BreXis Short Stem, standard	Size 3	95.7
160.00.04	BreXis Short Stem, standard	Size 4	99
160.00.05	BreXis Short Stem, standard	Size 5	102.4
160.00.06	BreXis Short Stem, standard	Size 6	105.8
160.00.07	BreXis Short Stem, standard	Size 7	109.6
160.00.08	BreXis Short Stem, standard	Size 8	112.5
160.00.09	BreXis Short Stem, standard	Size 9	115.9
160.00.10	BreXis Short Stem, standard	Size 10	119.29



#### Ceramic Ballheads

Ceramic femoral heads Stemox  $\varnothing 28$  mm,  $\varnothing 32$  mm and BIOLOX<sup>®</sup>forte  $\varnothing 28$  mm,  $\varnothing 32$  mm und  $\varnothing 36$  mm are available in sizes S, M and L. BIOLOX<sup>®</sup>delta and BIOLOX<sup>®</sup>OPTION are available in diameters  $\varnothing 28$  mm,  $\varnothing 32$  mm,  $\varnothing 36$  mm and  $\varnothing 40$  mm in sizes S, M, L and XL.

In case of a possible replacement, a BIOLOX Option femoral head should be used. Ceramic/ceramic pairs only from the same manufacturer may be used.



#### Metal Ballheads

Metal femoral ballheads for BreXis Short Stem in diameters  $\varnothing 28$ mm,  $\varnothing 32$ mm,  $\varnothing 36$ mm and  $\varnothing 40$ mm are available in sizes S, M, L and XL.

## 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.

# 8. BreXis Instruments

## 8.1 Preparation

Cleaning max. one hour after use.

Sterilization is carried out in the assembled state.

Accessories and spare parts can be obtained from the medical adviser responsible for you.



Fig.15: BreXis- Compactor Instrument set



Fig.16: BreXis- Rasp Instrument set

Some BreXis instruments can be disassembled for easier cleaning and maintenance. Please see the component disassembly / assembly instructions. The subsequent sterilization is effected in the assembled state.

## 8.2 Repair

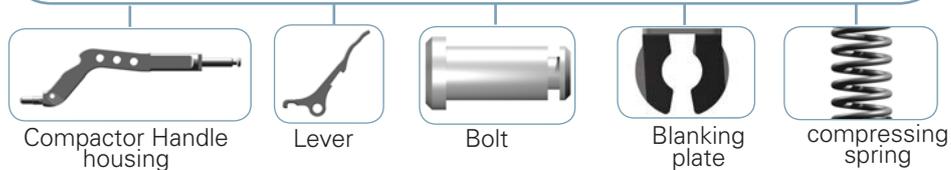
Repairs may only be carried out from persons authorized by Stemcup.

### **Defective instruments sending to:**

Stemcup Medical Products AG  
Reparaturen & Service  
Aargauerstrasse 180  
CH-8048 Zürich

## 9. Brexis Rasp Handle straight

Ref.: 60.160.30



### 9.1 Component disassembly instructions

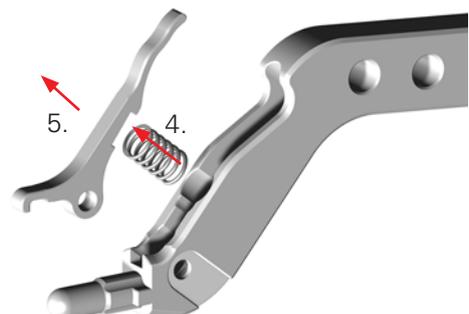
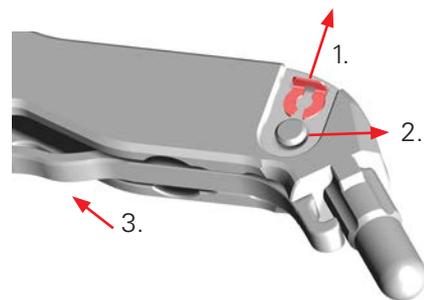
The blanking plate secures the bolt and can be dismantled without any tools .

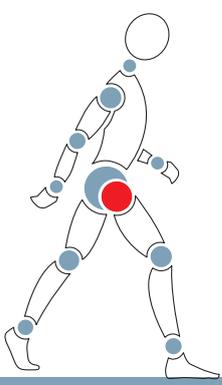
1. Align the lug on the blanking plate (1) parallel to the cut-out and remove it.

In order to facilitate the removal of the bolt, the bias of the compression spring should be lifted by pushing down the lever (3) a little.

After removing the bolt, lever and spring are loose. It is recommended to secure the lever with thumb in the housing to prevent some parts falling to the ground and / or losing them.

2. Remove the bolt (2).
3. Remove the lever (5) and the compression spring (4).





## 9. Brexis Rasp Handle streight

Ref.: 60.160.30



### 9.2 Component assembly instructions

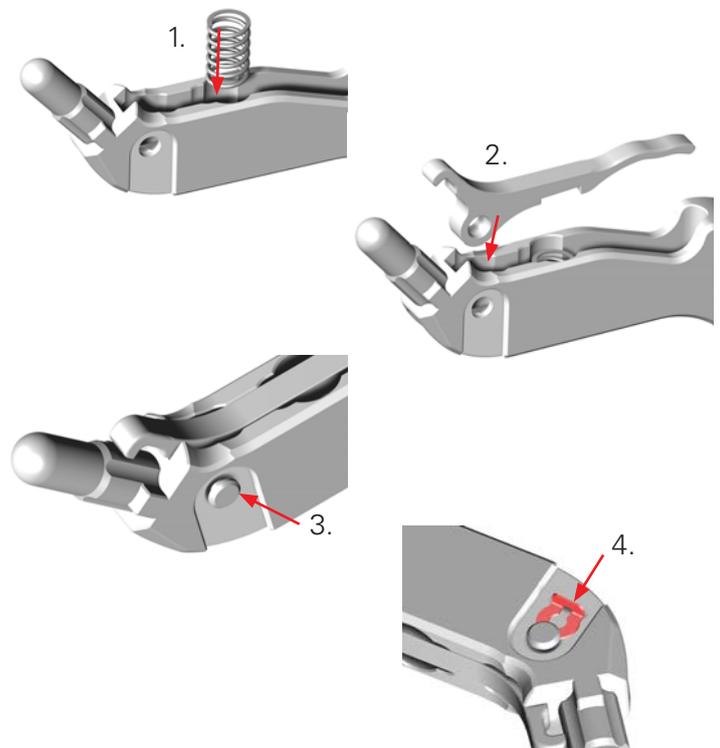
1. Set the compression spring (1) in the compactor handle housing.
2. Place the lever (2) into the housing.

Hold the lever pushed down, until the bore of the lever and the handle housing compactor are aligned axially, so that the bolt can be introduced.

3. Place the bolt (3) into the housing.

The bolt must be pushed completely into the compactor handle housing, to be able to put the blanking plate on the end of the bolt.

4. Set the blanking plate (4) on the end of the bolt.



### 9.3 Instruments labeling

The instruments and the corresponding parts are labeled individually with the same part number and the specific part number.

For example BreXis Compactor handle (Fig. 18):

Housing:	60.160.30-A1	Part I/III
Bolt:	60.160.30-A1	Part II/III
Lever:	60.160.30-A1	Part III/III



Fig.18: Labeling example

## 10. *Brexis compactor handle straight, short*

Ref.: 60.160.40



### 10.1 *Disassembly instructions*

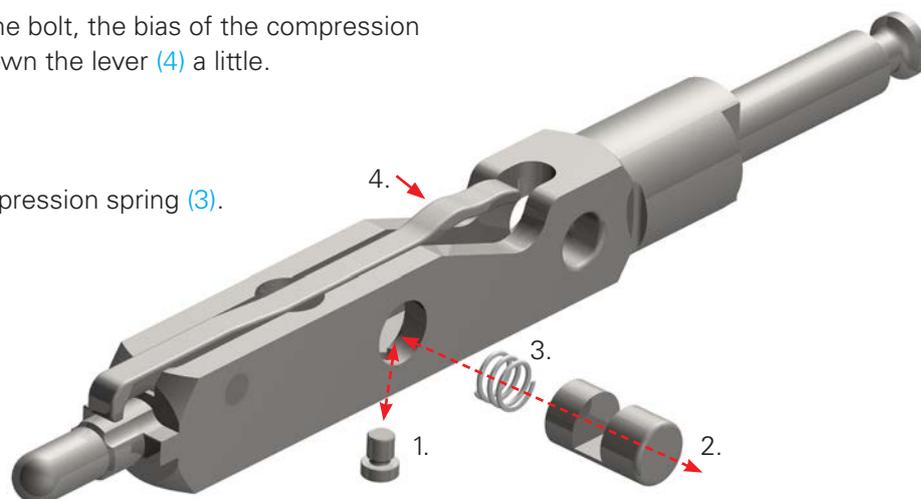
The locking screw secures the bolt and can be dismantled without any tools.

Turn the locking screw counterclockwise to detach it.

1. Detach and remove the locking screw (1).

In order to facilitate the removal of the bolt, the bias of the compression spring should be lifted by pushing down the lever (4) a little.

2. Remove the bolt (2).
3. Carefully remove the compression spring (3).



### 10.2 *Component assembly instructions*

Hold the lever pushed down until the bore of the lever and housing are axially aligned, so that the compression spring and the bolt can be introduced.

1. Set the compression spring (3) in the compactor handle housing.
2. Place the bolt (2) into the compactor handle housing.

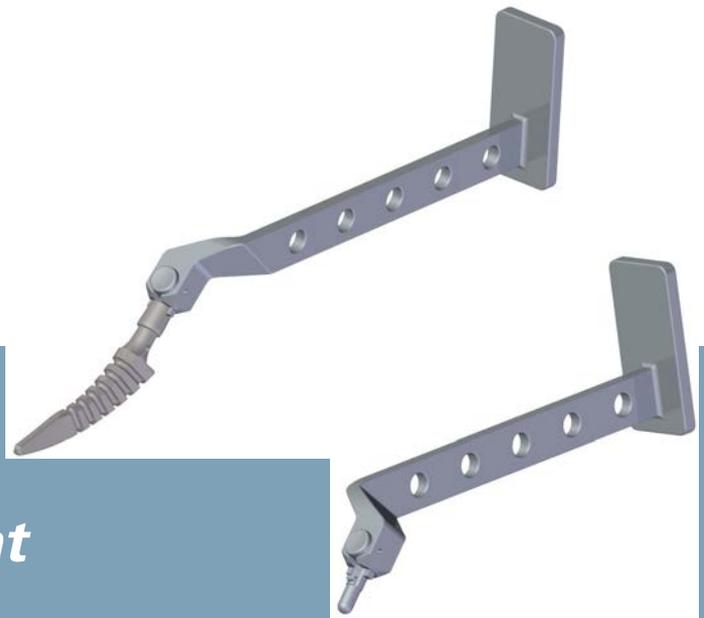
The bolt must be completely pushed into the housing in order to insert the locking screw can.

3. Put the locking screw (1) into the compactor housing.

To tighten the locking screw turn it clockwise.

## 11. BreXis- Adaptor with impact plate left / right

Ref.: 60.160.41 / Ref.: 60.160.42



### 11.1 Disassembly instructions

#### Caution:

For the disassembly / assembly it is required the hexagon socket wrench with 2.5 mm width.

The bias of the compression spring should be repealed to facilitate the dismantling by holding the push button down a little.

To prevent the loss of the compression spring, hold the push button gently by removing the hexagon socket screw.

1. Unclip the hexagon socket screw (1) with the hexagon socket wrench.
2. Remove the push button (2).
3. Remove the compression spring (3) from the push button (2).

### 11.2 Assembly instructions

1. Set the compression spring (3) in the push button (2).
2. Set the push button (2) with the spring in the adaptor bore.

To insert the hexagon socket screw, hold the push button pressed.

3. Put the hexagon socket screw (1) into the thread.

Fix the hexagon socket screw with the hexagon socket wrench with 2.5 mm width.

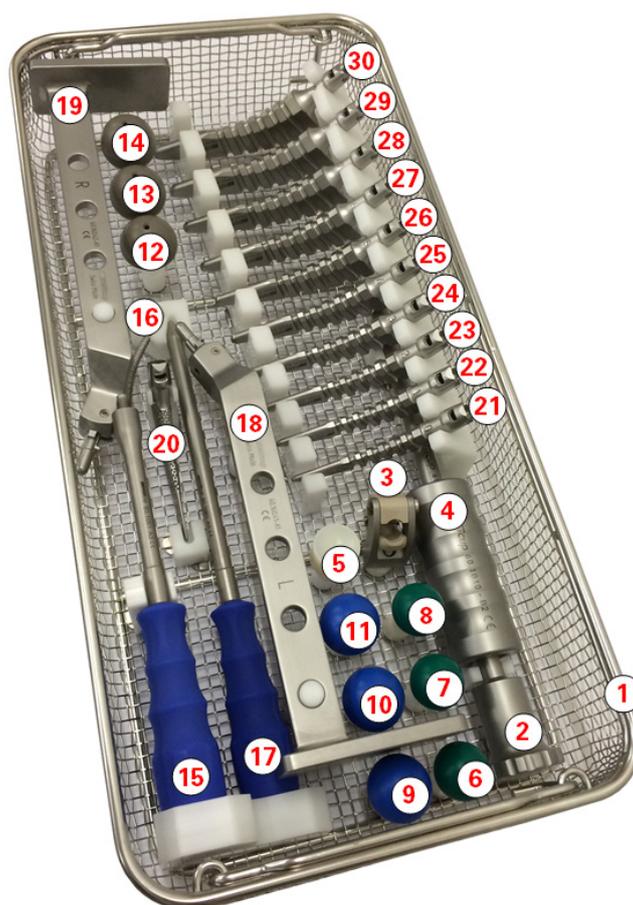


# 12. Instruments Ordering Information



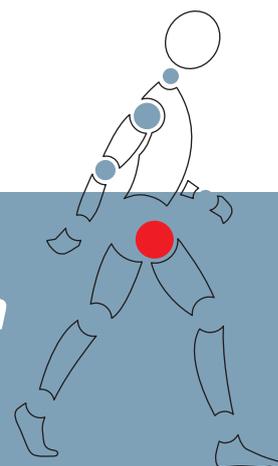
## 12.1 BreXis- Compactor Instrument set

Pos.	Ref.	Description
1	60.160.801-90	Empty tray with inserts
2	60.1064	Extractor
3	60.160.33	Extraction instrument BreXis
4	60.1010	Slide weight for extractor
5	60.1008	Impactor attachment - ball
6	60.28.11	Trial head 28 S for stem taper
7	60.28.12	Trial head 28 M for stem taper
8	60.28.13	Trial head 28 L for stem taper
9	60.32.11	Trial head 32 S for stem taper
10	60.32.12	Trial head 32 M for stem taper
11	60.32.13	Trial head 32 L for stem taper
12	60.36.11	Trial head 36 S for stem taper
13	60.36.12	Trial head 36 M for stem taper
14	60.36.13	Trial head 36 L for stem taper
15	60.1061	Impactor handle
16	60.160.34	Opening rasp
17	60.1060	Stem impactor SR2
18	60.160.41	BreXis Comp./Rasp. adaptor, left
19	60.160.42	BreXis Comp./Rasp. adaptor, right
20	60.160.15	Pre-reamer
21	60.160.00	BreXis Compactor size 0
22	60.160.01	BreXis Compactor size 1
23	60.160.02	BreXis Compactor size 2
24	60.160.03	BreXis Compactor size 3
25	60.160.04	BreXis Compactor size 4
26	60.160.05	BreXis Compactor size 5
27	60.160.06	BreXis Compactor size 6
28	60.160.07	BreXis Compactor size 7
29	60.160.08	BreXis Compactor size 8
30	60.160.09	BreXis Compactor size 9
optional	60.1059	Impaction attachment
optional	60.1075	Crossbar for rasphandle
optional	60.160.30	Impacting adaptor straight
optional	60.160.40	BreXis Comp./Rasp. adaptor, short
optional	60.40.11	Trial head 40 S for stem taper
optional	60.40.12	Trial head 40 M for stem taper
optional	60.40.13	Trial head 40 L for stem taper
optional	60.40.14	Trial head 40 XL for stem taper
optional	60.28.14	Trial head 28 XL for stem taper
optional	60.32.14	Trial head 32 XL for stem taper
optional	60.36.14	Trial head 36 XL for stem taper

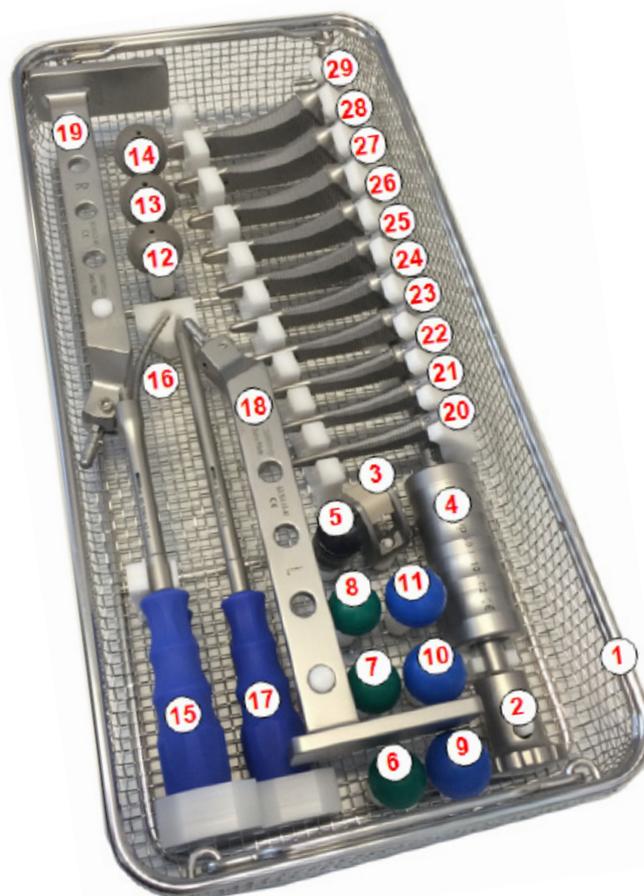


# 12. Instruments Ordering Information

## 12.2 BreXis- Rasp Instrument set



Pos.	Ref.	Description
1	60.160.801-90	Empty tray with inserts
2	60.1064	Extractor
3	60.160.33	Extraction instrument BreXis
4	60.1010	Slide weight for extractor
5	60.1008	Impactor attachment - ball
6	60.28.11	Trial head 28 S for stem taper
7	60.28.12	Trial head 28 M for stem taper
8	60.28.13	Trial head 28 L for stem taper
9	60.32.11	Trial head 32 S for stem taper
10	60.32.12	Trial head 32 M for stem taper
11	60.32.13	Trial head 32 L for stem taper
12	60.36.11	Trial head 36 S for stem taper
13	60.36.12	Trial head 36 M for stem taper
14	60.36.13	Trial head 36 L for stem taper
15	60.1061	Impactor handle
16	60.160.34	Opening rasp
17	60.1060	Stem impactor SR2
18	60.160.41	BreXis Comp./Rasp. adaptor, left
19	60.160.42	BreXis Comp./Rasp. adaptor, right
20	61.160.00	BreXis Rasp size 0
21	61.160.01	BreXis Rasp size 1
22	61.160.02	BreXis Rasp size 2
23	61.160.03	BreXis Rasp size 3
24	61.160.04	BreXis Rasp size 4
25	61.160.05	BreXis Rasp size 5
26	61.160.06	BreXis Rasp size 6
27	61.160.07	BreXis Rasp size 7
28	61.160.08	BreXis Rasp size 8
29	61.160.09	BreXis Rasp size 9
optional	61.160.10	BreXis Rasp size 10
optional	60.1059	Impaction attachment
optional	60.1075	Crossbar for rasphandle
optional	60.160.30	Impacting adaptor straight
optional	60.160.40	BreXis Comp./Rasp. adaptor, short
optional	60.40.11	Trial head 40 S for stem taper
optional	60.40.12	Trial head 40 M for stem taper
optional	60.40.13	Trial head 40 L for stem taper
optional	60.40.14	Trial head 40 XL for stem taper
optional	60.28.14	Trial head 28 XL for stem taper
optional	60.32.14	Trial head 32 XL for stem taper
optional	60.36.14	Trial head 36 XL for stem taper





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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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