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## 1. Introduction

In SCS/SCL Stem and SCR Revision Stem with an extensive fixation, we offer long-proven implants that are made of forged titanium alloy Ti6Al7Nb according to ISO 5832-11 / ASTM F1295 and Ti6Al4V Titanium-vanadium according to ISO 5832-3 / ASTM F136 / ASTM F1472 and, thanks to their corundum-blasted roughened surface, exhibit an optimal osseointegration.

The long-proven rectangular double-tapered design ensures a high rotational, primary and secondary stability. These are prerequisites for an early postoperative weight-bearing and a maximum restoration of the patient's mobility.

This stem system can be used with all age groups and is suitable both for primary implantations and revision procedures.

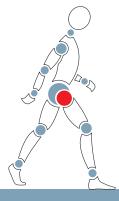
The standard SCS Stem is available in 12 sizes (01-10), the lateral SCL Stem in 9 sizes (1-9) and the SCR Revision Stem – in 9 sizes (3-11).

#### **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.







# 2. System description

### 2.1 Prosthesis design

- Standard, lateralised and revision design
- Double-tapered straight stem with rectangular profile
- Fixation in meta-diaphyseal region
- 12/14 Eurocone
- Material: forged alloy Ti6Al7Nb, ISO 5832-11 / Ti6Al4V ISO 5832-3
- Optional Ti/HA coating
- Corundum-blasted surface with a roughness Ra of 4 6 μm

### 2.1.1 Standard SCS Stem

- 12 sizes (01-10)
- CCD angle 131°

### 2.1.2 Lateral SCL Stem

- 9 sizes (1-9)
- CCD angle 127°

### 2.1.3 SCR Revision Stem

- 9 sizes (3-11)
- CCD angle 131°



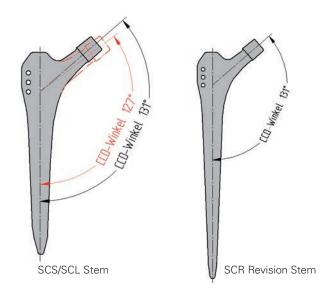




# 2. System description

### 2.2 CCD Angle

The standard SCS Stem as well as the SCR Revision Stem have a 131° degree CCD angle while the lateral SCL Stem has a 127° degree CCD angle.

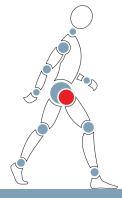


#### 2.3 Instrumentation

A simple and well-arranged instrumentation allows a convenient and correct implantation of the SCS/SCL stem. After the reaming of the femur there is a possibility to determine the correct size and length with the trial stem or directly with the trial rasp. An exact match between the instrument and the implant allows a reliable, efficient and precise work.

Long rasps are available on requests.





## 3. 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. The following criteria should be taken into account to ensure optimum durability of the SCS/SCL/SCR stem:

#### 3.1 Indications

It follows, from the above statements, that a prosthesis is indicated in cases where some of the following

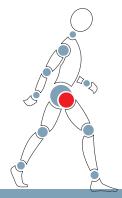
five basic conditions are fulfilled:

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



## 3. Indications / Contraindications / E-IFU

#### 3.2 Contraindications

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

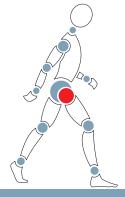
- acute or chronic infection (local or systemic)
- severe muscular, neurological or vascular disease threatening the extremity concerned
- loss of bone structure or poor quality of bone, precluding proper anchorage of the implant
- any concomitant disease which may compromise the function of the implant
- 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 <a href="mailto:administration@stemcup.ch">administration@stemcup.ch</a> or send us a fax on the appropriate fax numbers of Stemcup Switzerland, Germany or Austria.



# 4. Preoperative Planning

Using the available X-ray templates, it is possible to plan the stem size, the stem position as well as the resection height.

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



# 5. Surgical technique

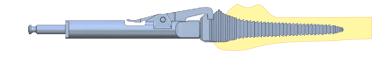
### 5.1 Box chisel

Open the medullary canal.

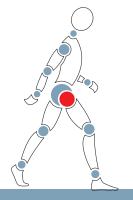


### 5.2 Adapter with lever / trial rasp

- 1. Rasp the femur stepwise to the suitable implant size.
- 2. The rasping procedure can be optionally performed with the slide hammer or the rasping machine.
- 3. Detach the adapter from the rasp by pressing the lever.







# 5. Surgical technique

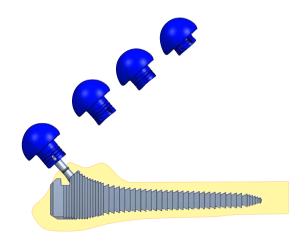
#### Stem trial 5.3

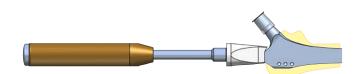
The rasp serves as trial implant. For surgical procedures with long rasps, appropriate trial stems are available.

- 1. Put on the trial taper. There is a choice of trial tapers for SCS Stem and SCR Revision Stem (CCD angle 131°) or SCL Stem (CCD angle 127°).
- 2. Put a trial head on the rasp. (ø28 mm, ø32 mm, ø36 mm and ø40 mm in neck lengths S/M/L/XL)
- 3. Perform a trial reduction.
- 4. Put on the adapter with lever. Knock out the rasp with the help of the slide hammer or the rasping machine.

#### 5.4 Insertion of the original stem

- 1. Screw the stem driving attachment onto the impactor handle.
- 2. Insert the original stem by hand. The protective cap should remain on the taper when the stem is driven in.)
- 3. Drive the stem in with measured force using the stem impactor. (Take off the protective cap after ending the insertion procedure.)

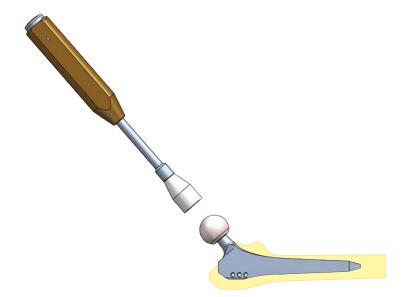




# 5. Surgical technique

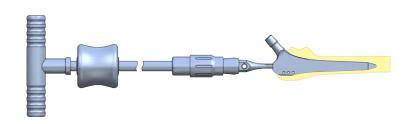
#### Femoral head impactor 5.5

- 1. Screw the impactor attachment onto the impactor.
- 2. Put on the femoral head.
- 3. Fix the head by lightly tapping on the mounted impactor. (Alternatively, the femoral head can be fixed by rotating it clockwise.)



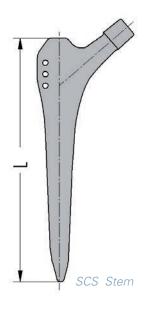
#### 5.6 Extracting screw

- 1. Screw the extracting screw into the stem.
- 2. Extract the stem with the help of the slide hammer.



# Implants ordering overview

### 6.1 SCS/SCL/SCR Stem - Ref. No.: Ti6AI7Nb



				Longar	
Size	SCS Stem	SCL Stem	SCR Stem	SCS/SCL	SCR
01	120.00.15			129	
0	120.00.00			132	
1	120.00.01	123.00.01		136	
2	120.00.02	123.00.02		140	
3	120.00.03	123.00.03	126.00.03	144	195
4	120.00.04	123.00.04	126.00.04	148	200
5	120.00.05	123.00.05	126.00.05	153	206
6	120.00.06	123.00.06	126.00.06	157	212
7	120.00.07	123.00.07	126.00.07	164	218
8	120.00.08	123.00.08	126.00.08	169	224
9	120.00.09	123.00.09	126.00.09	175	230
10	120.00.10		126.00.10	181	237
11			126.00.11		243

Length in mm



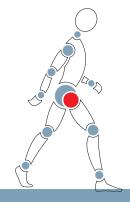


### Ceramic femoral heads

Ceramic femoral heads Stemox, BIOLOX®forte, BIOLOX®delta und BIOLOX®OPTION are available in diameters ø28 mm, ø32 mm, ø36 mm and ø40 mm in sizes S, M and L (XL in BIOLOX®delta und BIOLOX®OPTION). 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 femoral heads

Metal femoral heads are available in diameters ø28 mm, ø32 mm, ø36 mm and ø40 mm in sizes S, M, L, XL and XXL.



# 6. Implants ordering overview



6.2	Ref. No.:	Ti6AI7Nb-	Ti/HA		
				Length	in mm
Size	SCS Stem	SCL Stem	SCR Stem	SCS/SCL	SCR
01	112.00.15			129	
0	112.00.00			132	
1	112.00.01	113.00.01		136	
2	112.00.02	113.00.02		140	
3	112.00.03	113.00.03	114.00.03	144	195
4	112.00.04	113.00.04	114.00.04	148	200
5	112.00.05	113.00.05	114.00.05	153	206
6	112.00.06	113.00.06	114.00.06	157	212
7	112.00.07	113.00.07	114.00.07	164	218
8	112.00.08	113.00.08	114.00.08	169	224
9	112.00.09	113.00.09	114.00.09	175	230
10	112.00.10		114.00.10	181	237
11			114.00.11		243



### 6.3 Ref. No.: Ti6AI4V

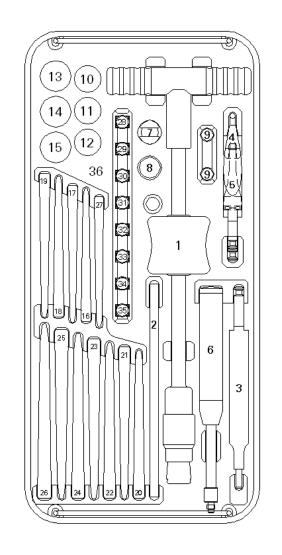
				Length	in mm
Size	SCS Stem	SCL Stem	SCR Stem	SCS/SCL	SCR
01	127.00.15			129	
0	127.00.00			132	
1	127.00.01	128.00.01		136	
2	127.00.02	128.00.02		140	
3	127.00.03	128.00.03	129.00.03	144	195
4	127.00.04	128.00.04	129.00.04	148	200
5	127.00.05	128.00.05	129.00.05	153	206
6	127.00.06	128.00.06	129.00.06	157	212
7	127.00.07	128.00.07	129.00.07	164	218
8	127.00.08	128.00.08	129.00.08	169	224
9	127.00.09	128.00.09	129.00.09	175	230
10	127.00.10		129.00.10	181	237
11			129.00.11		243

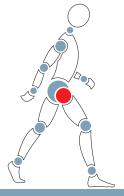
Instruments - Sterility The instruments are not sterile when they are delivered. Before use, they must be reprocessed and sterilized according to Stemcup's Instrument-Leaflet. The instruction leaflet for instruments "Recommendation Care - Cleaning - Maintenance - Sterilization" is available upon request, resp. is 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.

### Instruments ordering overview 7.

#### 7.1 Instruments, trial rasp tray - SCS/SCL Stem

Pos.	Ref.No.	Description
1	60.1000	Slide hammer
2	60.1001	Box chisel, angled
3	60.1002	Adapter with lever
4	60.1003	Extracting hook
5	60.1004	Extracting screw
6	60.1006	Impactor handle
7	60.1007	Impactor attachment - stem
8	60.1008	Impactor attachment – ball
9	60.1040	Trial taper (2x)
10	60.28.11	Trial head 28 S for stem taper
11	60.28.12	Trial head 28 M for stem taper
12	60.28.13	Trial head 28 L for stem taper
13	60.32.11	Trial head 32 S for stem taper
14	60.32.12	Trial head 32 M for stem taper
15	60.32.13	Trial head 32 L for stem taper
16	61.120.00	SCS trial rasp, size 0
17	61.120.01	SCS trial rasp, size 1
18	61.120.02	SCS trial rasp, size 2
19	61.120.03	SCS trial rasp, size 3
20	61.120.04	SCS trial rasp, size 4
21	61.120.05	SCS trial rasp, size 5
22	61.120.06	SCS trial rasp, size 6
23	61.120.07	SCS trial rasp, size 7
24	61.120.08	SCS trial rasp, size 8
25	61.120.09	SCS trial rasp, size 9
26	61.120.10	SCS trial rasp, size 10
27	61.120.15	SCS trial rasp, size 01
28	61.120.32	SCL trial taper 131°/ 127°, size 1+2
29	61.120.33	SCL trial taper 131°/ 127°, size 3
30	61.120.34	SCL trial taper 131°/ 127°, size 4
31	61.120.35	SCL trial taper 131°/ 127°, size 5
32	61.120.36	SCL trial taper 131°/ 127°, size 6
33	61.120.37	SCL trial taper 131°/ 127°, size 7
34	61.120.38	SCL trial taper 131°/ 127°, size 8
35	61.120.39	SCL trial taper 131°/ 127°, size 9
36	61.120.801.01-90	Empty tray with inserts

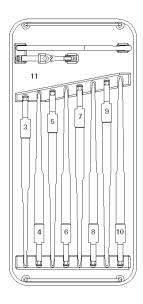




# Instruments ordering overview

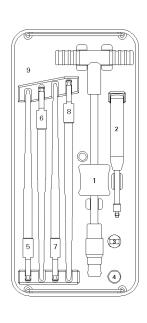
#### Long rasp tray 1 for - SCS/SCL Stem 7.2

Pos.	Ref.No.	Description
1	60.1001	Box chisel, angled
2	60.1004	Extracting instrument (screw)
3	60.122.15	SC/SCS/SCL Long rasp, size 01
4	60.122.00	SC/SCS/SCL Long rasp, size 0
5	60.122.01	SC/SCS/SCL Long rasp, size 1
6	60.122.02	SC/SCS/SCL Long rasp, size 2
7	60.122.03	SC/SCS/SCL Long rasp, size 3
8	60.122.04	SC/SCS/SCL Long rasp, size 4
9	60.122.05	SC/SCS/SCL Long rasp, size 5
10	60.122.06	SC/SCS/SCL Long rasp, size 6
11	60.120.801.01-90	Empty tray with inserts 1 - long rasp for SCS/SCL



#### Long rasp tray 2 for SCS/SCL Stem 7.3

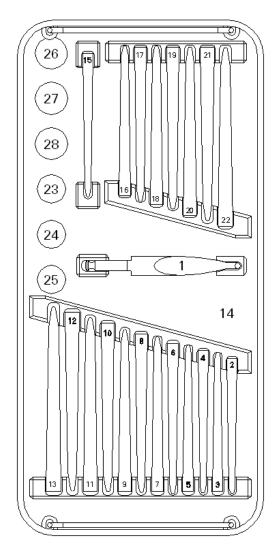
Pos.	Ref.No.	Description
1	60.1000	Slide hammer
2	60.1006	Impactor handle
3	60.1007	Impactor attachment - stem
4	60.1008	Impactor attachment – ball
5	60.122.07	SC/SCS/SCL Long rasp, size 7
6	60.122.08	SC/SCS/SCL Long rasp, size 8
7	60.122.09	SC/SCS/SCL Long rasp, size 9
8	60.122.10	SC/SCS/SCL Long rasp, size 10
9	60.120.801.02-90	Empty tray with inserts 2 - long rasp for SCS/SCL

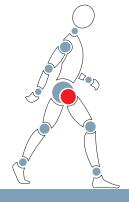


# Instruments ordering overview

#### Instruments, trial stem tray - SCS/SCL Stem 7.4

Pos.	Ref.No.	Description
1	60.1003	Extracting hook
2	60.220.00	SCS trial stem, standard, size 0
3	60.220.01	SCS trial stem, standard, size 1
4	60.220.02	SCS trial stem, standard, size 2
5	60.220.03	SCS trial stem, standard, size 3
6	60.220.04	SCS trial stem, standard, size 4
7	60.220.05	SCS trial stem, standard, size 5
8	60.220.06	SCS trial stem, standard, size 6
9	60.220.07	SCS trial stem, standard, size 7
10	60.220.08	SCS trial stem, standard, size 8
11	60.220.09	SCS trial stem, standard, size 9
12	60.220.10	SCS trial stem, standard, size 10
13	60.220.15	SCS trial stem, standard, size 01
14	60.220.801.01-90	Empty tray with inserts – trial stem for SCS/SCL
15	60.223.02	SCL trial stem, lateral, size 2
16	60.223.03	SCL trial stem, lateral, size 3
17	60.223.04	SCL trial stem, lateral, size 4
18	60.223.05	SCL trial stem, lateral, size 5
19	60.223.06	SCL trial stem, lateral, size 6
20	60.223.07	SCL trial stem, lateral, size 7
21	60.223.08	SCL trial stem, lateral, size 8
22	60.223.09	SCL trial stem, lateral, size 9
23	60.28.11	Trial head 28 S for stem taper
24	60.28.12	Trial head 28 M for stem taper
25	60.28.13	Trial head 28 L for stem taper
26	60.32.11	Trial head 32 S for stem taper
27	60.32.12	Trial head 32 M for stem taper
28	60.32.13	Trial head 32 L for stem taper

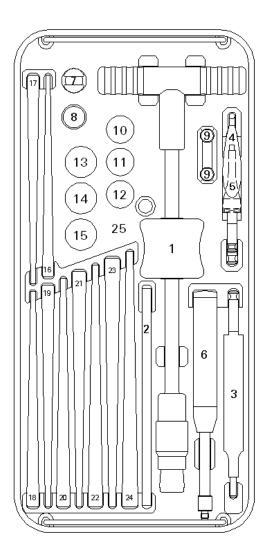




#### **7**. Instruments ordering overview

#### Instruments, revision rasp tray - SCR Revision Stem 7.5

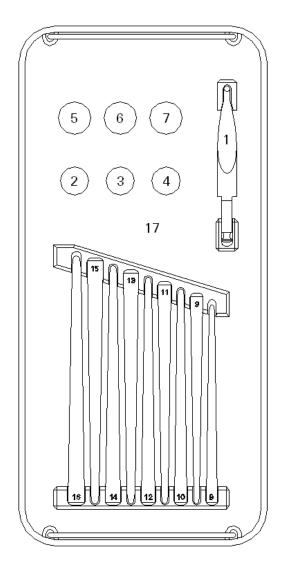
Pos.	Ref.No.	Description
1	60.1000	Slide hammer
2	60.1001	Box chisel, angled
3	60.1002	Adapter with lever
4	60.1003	Extracting hook
5	60.1004	Extracting screw
6	60.1006	Impactor handle
7	60.1007	Impactor attachment - stem
8	60.1008	Impactor attachment – ball
9	60.1040	Trial taper (2x)
10	60.28.11	Trial head 28 S for stem taper
11	60.28.12	Trial head 28 M for stem taper
12	60.28.13	Trial head 28 L for stem taper
13	60.32.11	Trial head 32 S for stem taper
14	60.32.12	Trial head 32 M for stem taper
15	60.32.13	Trial head 32 L for stem taper
16	62.126.03	SCR revision rasp, size 3
17	62.126.04	SCR revision rasp, size 4
18	62.126.05	SCR revision rasp, size 5
19	62.126.06	SCR revision rasp, size 6
20	62.126.07	SCR revision rasp, size 7
21	62.126.08	SCR revision rasp, size 8
22	62.126.09	SCR revision rasp, size 9
23	62.126.10	SCR revision rasp, size 10
24	62.126.11	SCR revision rasp, size 11
25	62.126.801.01-90	Empty tray with inserts



# 7. Instruments ordering overview

#### Instruments, trial stem tray - SCR Revision Stem 7.6

Pos.	Ref.No.	Description
1	60.1003	Extracting hook
2	60.28.11	Trial head 28 S for stem taper
3	60.28.12	Trial head 28 M for stem taper
4	60.28.13	Trial head 28 L for stem taper
5	60.32.11	Trial head 32 S for stem taper
6	60.32.12	Trial head 32 M for stem taper
7	60.32.13	Trial head 32 L for stem taper
8	62.220.03	SCR trial stem, revision, size 3
9	62.220.04	SCR trial stem, revision, size 4
10	62.220.05	SCR trial stem, revision, size 5
11	62.220.06	SCR trial stem, revision, size 6
12	62.220.07	SCR trial stem, revision, size 7
13	62.220.08	SCR trial stem, revision, size 8
14	62.220.09	SCR trial stem, revision, size 9
15	62.220.10	SCR trial stem, revision, size 10
16	62.220.11	SCR trial stem, revision, size 11
17	62.220.801.01-90	Empty tray with inserts – trial stem for SCR





# **Instruments ordering overview**

#### Instrumenttray for SCS Stem with SCS rasp with Stelia connection 7.7

Pos.	Ref.No.	Description	Pos.	Ref.No.	Description
1	60.150.30	Stelia box chisel	23	60.32.11	Trial-head Ø32 S
2	60.1061	Impactor handle	24	60.32.12	Trial-head Ø32 M
3	60.1007	Impactor attachment for stems	25	60.32.13	Trial-head Ø32 L
4	60.1008	Impactor attachment for ball heads	26	60.32.14	Trial-head Ø32 XL
5	60.1059	Impactor attachment for adapter			
6	60.150.36	Stelia Rasp handle right with 30mm offset	27	60.36.11	Trial-head Ø36 S
7	60.150.37	Stelia Rasp handle left with 30mm offset	28	60.36.12	Trial-head Ø36 M
8	60.151.00	Stelia trial taper standard Sz 01+0	29	60.36.13	Trial-head Ø36 L
9	60.151.01	Stelia trial taper standard Sz 1+2	30	60.36.14	Trial-head Ø36 XL
10	60.151.02	Stelia trial taper standard Sz 3+4	31	60.150.31	Opening Rasp
11	60.151.03	Stelia trial taper standard Sz 5+6	32	62.120.15	SCS rasp with Stelia connection SZ 01
12	60.151.04	Stelia trial taper standard Sz 7+8	33	62.120.00	SCS rasp with Stelia connection Sz 0
13	60.151.05	Stelia trial taper standard Sz 9+10	34	62.120.01	SCS rasp with Stelia connection SZ 1
14	60.151.06	Stelia trial taper lateralized Sz 1+2	35	62.120.02	SCS rasp with Stelia connection SZ 2
15	60.151.07	Stelia trial taper lateralized Sz 3+4	36	62.120.03	SCS rasp with Stelia connection SZ 3
16	60.151.08	Stelia trial taper lateralized Sz 5+6	37	62.120.04	SCS rasp with Stelia connection SZ 4
17	60.151.09	Stelia trial taper lateralized Sz 7+8	38	62.120.05	SCS rasp with Stelia connection SZ 5
18	60.151.10	Stelia trial taper lateralized Sz 9	39	62.120.06	SCS rasp with Stelia connection SZ 6
19	60.28.11	Trial-head Ø28 S	40	62.120.07	SCS rasp with Stelia connection SZ 7
20	60.28.12	Trial-head Ø28 M	41	62.120.08	SCS rasp with Stelia connection SZ 8
21	60.28.13	Trial-head Ø28 L	42	62.120.09	SCS rasp with Stelia connection SZ 9
22		Trial-head Ø28 XL	43	62.120.10	SCS rasp with Stelia connection SZ 10
<b>ZZ</b>	60.28.14	IIId-IIEdu WZO AL	44	60.150.801.01-90	Instrumenttray for Stelia/SCS Stem

#### Additional Instruments 7.8

Ref.No.	Description
60.1000	Slide hammer
60.1004	Extraction screw
60.150.34	Stelia Rasp handle right with 13mm offset
60.150.35	Stelia Rasp handle left with 13mm offset
60.40.11	Trial Ballhead ø40 S
60.40.12	Trial Ballhead ø40 M
60.40.13	Trial Ballhead ø40 L
60.40.14	Trial Ballhead ø40 XL

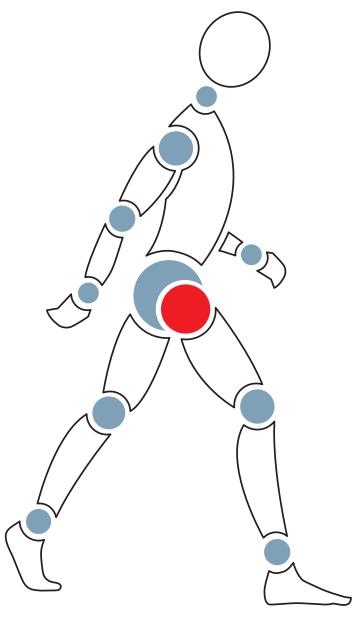
#### Nota Bene

The use of the Stelia Rasp handles with the rasps and the use of the trial tapers are described in the Stelia surgical technique.





# Stemcup – central and close to you!



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