MATHYS
European Orthopaedics

Surgical technique

seleXys PC

Modular cementless press-fit cup system

For healthcare professional use only. The illustrated image does not represent a connection between the use of the medical device described, nor its performance.

***Preservation** in motion*

Building on our heritage
Moving technology forward
Step by step with our clinical partners
Towards a goal of preserving mobility

***Preservation** in motion*

As a Swiss company, Mathys is committed to this guiding principle and pursues a product portfolio with the goal of further developing traditional philosophies with respect to materials or design in order to address existing clinical challenges. This is reflected in our imagery: traditional Swiss activities in conjunction with continuously evolving sporting equipment.

Table of contents

Remark
Please make yourself familiar with the handling of the instruments, the product-related surgical technique and the warnings, the safety notes as well as the recommendations of the instruction leaflet before using an implant manufactured by Mathys Ltd Bettlach. Make use of the Mathys user training and proceed according to the recommended surgical technique.

Introduction

To move and live an active life – Mathys has lived by this maxim since 1963. With this in mind we are able to achieve our objectives: To give back a life of movement to as many people as possible and to maintain it. Our vast experience in the field of orthopaedics makes a substantial contribution.

The seleXys PC Cup is the second generation of beaded porous cups that have been in use in the Mathys portfolio since 2003.

The seleXys PC Cup offers a wide range of components that corresponds with the individual patient's anatomical conditions and the functional requirements of the hip joint.
With two different polyethylene options (UHMWPE, vitamys Vitamin-E enriched highly crosslinked PE) as well as an advanced ceramic composite material for ceramic-on-ceramic articulation (ceramys), the portfolio includes several enhanced bearing options that also allow use of bigger head diameters for increased range of motion and joint stability.

The seleXys Cup has been developed to restore the individual patient anatomy. The instrument set allows the orthopedic surgeon to implant the system using different surgical approaches.

1. Indications and contraindications

Indications
- Primary or secondary osteoarthritis of the hip
- Fracture of the femoral head or fracture of the femoral neck
- Necrosis of the femoral head

seleXys ceramic inlay
- Primary total hip arthroplasty in combination with a seleXys shell
- Revision surgery with a new seleXys shell

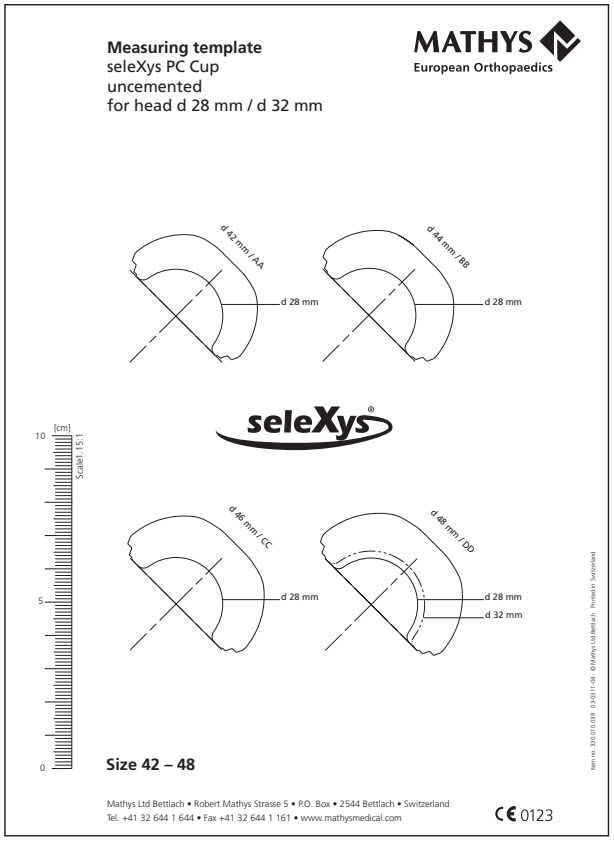
seleXys ceramic inlays may be used only in combination with Mathys ceramic femoral heads.

Contraindications
- Local and/or general infection
- Presence of factors jeopardising stable anchoring of the implant:
  – Bone loss or bone defects
  – Insufficient bone substance
- Presence of factors preventing osseointegration:
  – Irradiated bone (exception: preoperative irradiation for ossification prophylaxis)
  – Devascularisation
- Hypersensitivity to any of the materials used
- Severe soft tissue, nerve or vessel insufficiency that jeopardises the function and long-term stability of the implant

seleXys ceramic inlay
- Primary total hip arthroplasty with a cup not intended to be used with the seleXys ceramic inlay
- Revision surgery with the shell left in situ
- Ceramic inlay in combination with a metal head
- Ceramic inlay in combination with a ceramic head by any manufacturer other than Mathys Ltd Bettlach
- Do not use any hard-on-hard couples for cups with an inclination of under 40° or over 50° as, for example, in the treatment of dysplasia, since the implants could be damaged by subluxation processes or points of contact between the components
- Do not implant a hard-on-hard couple if there is a risk of impingement between the hip stem and the cup. In this case use a hard-on-soft couple

For further information, please refer to the instructions for use or ask your Mathys representative.

2. Preoperative planning



Preoperative templating can be performed on standard radiographs or with a digital planning system. The main goal is to plan the appropriate implant as well as its size and position, to restore the individual biomechanics of the hip joint. That way, potential problems can already be anticipated before surgery. In most cases, restoring hip biomechanics can be achieved by reconstructing the original hip rotation center, the leg length as well as the femoral and acetabular offset.[1] It is recommended to document the preoperative planning in the patient's file.

[1] Scheerlinck Th., «Primary hip arthroplasty templating on standard radiographs. A stepwise approach». Acta Orthop Belg, 2010. 76(4): p. 432-442

3. Surgical technique

Different standardized conventional approaches to the hip joint have been established over many years in orthopaedics, differing in patient position, orientation of skin incision and soft tissue intervals chosen to access the joint. During the last years, a variety of minimally invasive techniques have been developed to approach the hip joint.

Implantation of the seleXys PC cup is possible using different surgical approaches. The choice of the specific technique should be based on patient anatomy as well as the individual experience and preferences of the operating surgeon.

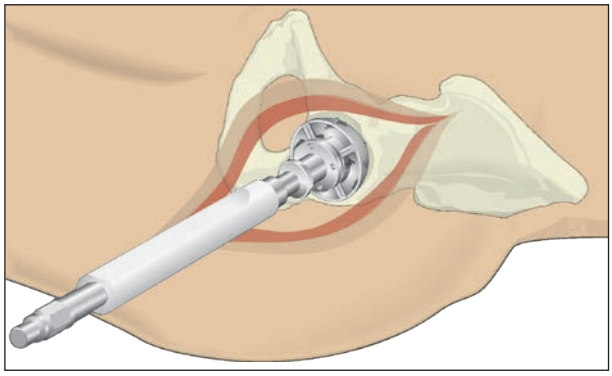


Fig. 1

Fig. 2

Femoral osteotomy
The femoral neck is exposed. The femoral neck resection level is related to the distance between the lesser and the greater trochanter and marked according to the preoperative planning.

Remarks
When anatomical conditions prevent head removal after a single neck cut, it is advisable to perform a double osteotomy of the femoral neck and remove the free bone block first. Then the femoral head is removed with a femoral head extractor.

Preparation of the acetabulum
When preparing the acetabulum, expose the osseous circumference and remove any capsular rests.

Carefully remove osteophytes. Deepen the acetabular cavity according to the depth defined in preoperative planning by using a small reamer size. Subsequently, proceed reaming in 1 – 2 mm increments until the subchondral bone is slightly vascularized.

For exact preparation of the acetabulum, it is recommended to use the handle with quick coupling and manually ream the final size (Fig. 1, 2).

Remarks
Take care to ream the acetabulum to the level defined in preoperative planning to ensure precise reconstruction of the patient anatomy.

Remarks
The true implant dimension is 2 mm bigger than the labelled size. The amount of press-fit used should be determined at the time of surgery and be based on bone quality. For most cases it is recommended to finalize reaming with an uneven reamer size and select a shell implant labelled 1 mm smaller than the last used reamer. This results in a 1 mm press-fit compared to the prepared acetabulum (Fig. 4).

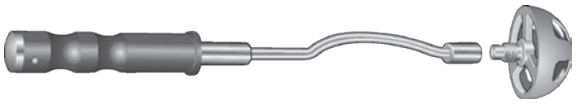
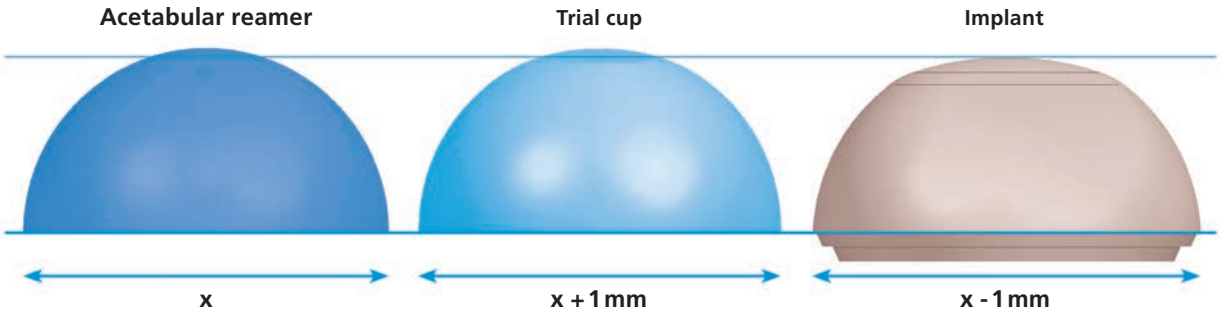


Fig. 3

Trialing and component sizing

The trial cup is 1 mm smaller than its labelled size. Select a trial cup that is labelled one size bigger than the last used reamer. The vision panel of the trial cup permits evaluation of the depth and sphericity of the reamed acetabulum (Fig. 3). Make sure that the bony coverage of the cup is sufficient.

For final implant size selection follow the example below (Fig. 4) and pick a seleXys PC shell that is labelled one size smaller than the last used reamer to achieve a 1 mm press-fit that in most cases results in sufficient primary stability.



Example for correct component sizing

	Acetabular reamer	Trial cup	seleXys PC shell
Labelled size	51 (x)	52 (x + 1)	50 (x - 1)
True dimension	51 mm	51 mm	52 mm

Fig. 4

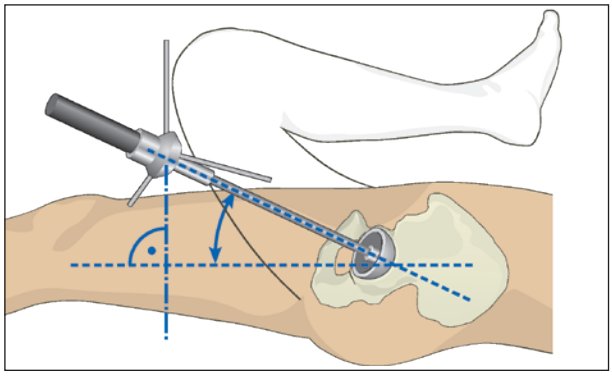


Fig. 5

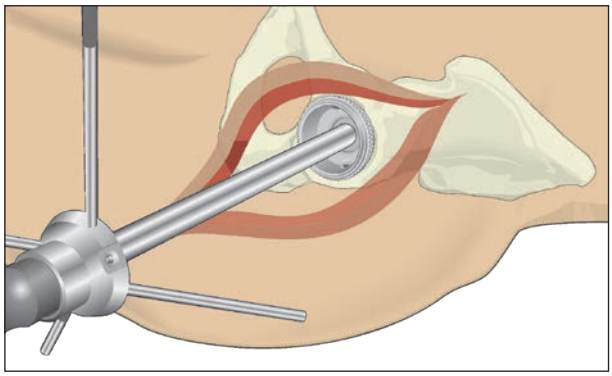


Fig. 6

Fig. 7

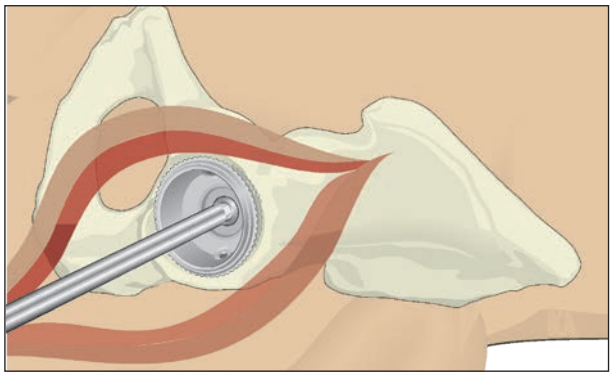


Fig. 8

Cup insertion

Connect the selected cup to the impactor. Ensure that the thread of the impactor is fully engaged in the dome hole of the shell.

Precise adjustment of inclination and anteversion is a prerequisite for complication-free functioning of the artificial hip joint; here the individual anatomy is to be considered. Generally, an inclination of 40°–50° and an anteversion of 10°–20° are recommended.

Use the positioning guide as a seating aid (Fig. 5, 6). It has been designed for an inclination of 45° and an anteversion of 20°.

Assure correct orientation of the screw holes when implanting the shell. Screw holes should be placed in the posterior superior and posterior inferior quadrants of the acetabulum.
Impact the shell into the final position defined by preoperative planning.
As an option, the seleXys shell post impactor can be used to finally seat the shell in the acetabulum.

Closing the central pole hole

To close the pole hole, put the pole cap onto the pole cap screwdriver (Fig. 7) and hand-tighten it in the pole hole of the shell (Fig. 8). The pole cap is delivered with the cup, but in a separate sterile packing.

Ensure that the pole cap is fully seated and verify that it does not protrude into the cup. Avoid overtightening.

Fig. 9

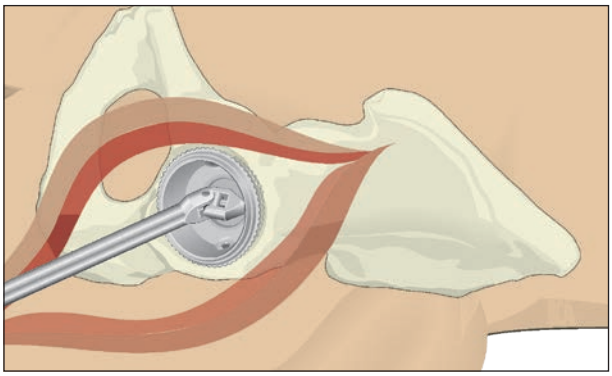


Fig. 10

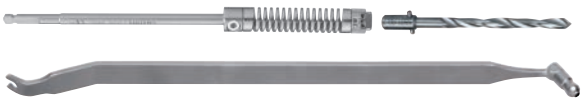


Fig. 11

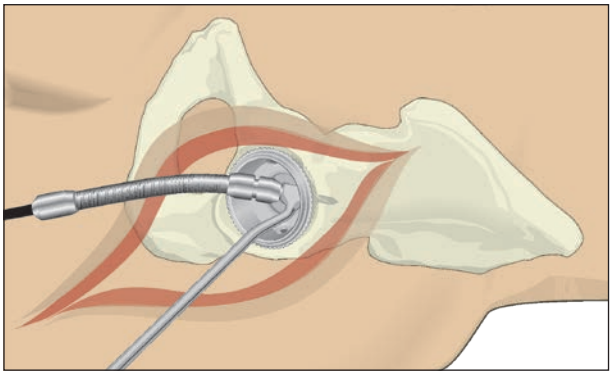


Fig. 12

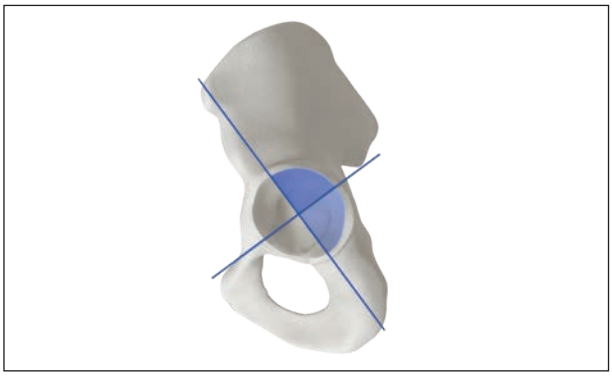


Fig. 13

Optional: Insertion of cancellous bone screws
As an option 5.7 mm cancellous bone screws can be used for additional fixation of the shell.

Screw hole covers are preassembled in all screw holes. Use the universal screwdriver (Fig. 9) to remove screw hole covers and open the screw holes as needed (Fig. 10).

Use a 3.2 mm drill bit with the flexible shaft (Fig. 11) and the drill guide for 5.7 mm screws to drill the holes (Fig. 12).

To minimise the risk of nerve and vessel injury, the position and drilling depths of the screw holes and the respective screw lengths must be selected taking into account the anatomy of the patient's pelvic area.
The screws must be placed in the postero- superior and postero-inferior quadrants (marked in blue) of the acetabulum (Fig. 13). [2]

[2] Wasielewski RC, Cooperstein LA, Kruger MP, Rubash HE. Acetabular anatomy and the transacetabular fixation of screws in total hip arthroplasty. J Bone Joint Surg. 1990: 72–A(4);501–508.

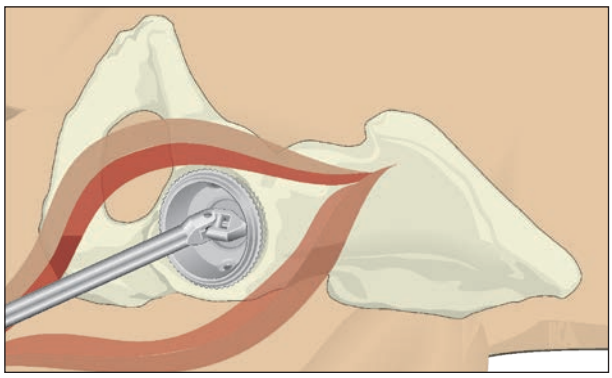


Fig. 14

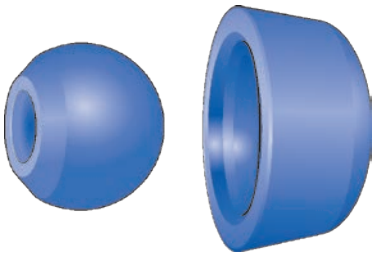


Fig. 15

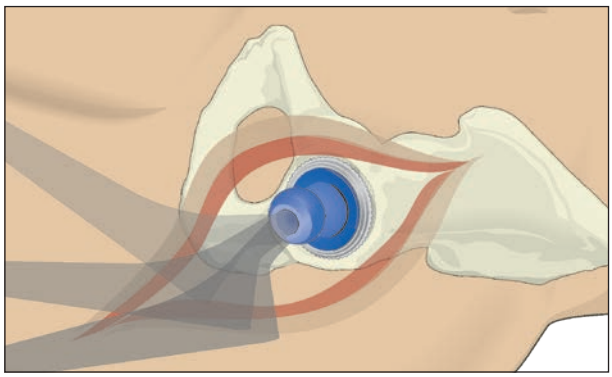


Fig. 16

Before screw insertion, use the depth gauge to measure the required screw length.

Use the universal screwdriver to insert screws (Fig. 14).

Only seleXys cancellous screws may be used. In order not to interfere with the anchoring of the inlay, care must be taken when inserting the cancellous screws that the screw heads are completely counter-sunk into the screw holes of the shell.

Trial reduction with trial inlays

Prepare the femoral canal according to the surgical technique of the stem. Select the trial inlay that corresponds to the size of the cup. Place the inlay manually and combine it with the matching trial head that is assembled on the femoral trial component or the final stem implant (Fig. 15).

The seleXys shells are labelled with the exterior size and a corresponding double letter code (e. g. 50/EE). The matching inlays are identified with the head diameter and matching letter code (e. g. 28/EE). The letter codes of the two components must match.

In the subsequent trial reduction, range of motion, joint stability and leg length are checked (Fig. 16). After trial reduction remove the trial inlay.

Do not implant a hard-on-hard couple if there is a risk of impingement between the hip stem and the cup. In this case, use a hard-on-soft couple.

Fig. 17

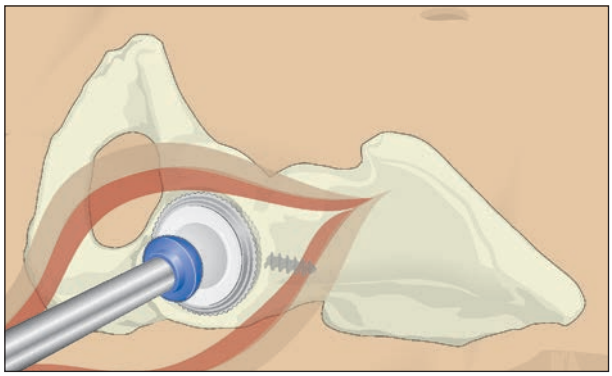


Fig. 18

Positioning the inlay

After cleaning and drying the inside of the shell, place the inlay manually into the shell and centre it. Prior to insertion of the inlay, verify that the letter codes on the shell and inlay are identical. Once the inlay is correctly seated, the PE or vitamys inlay is fixed in the shell by gently striking the inlay impactor (Figs. 17, 18).

Remarks

During its positioning, ensure that the inlay is not tilted. In the final position after impaction, the insert is flush with the edge of the shell.

After implantation of all implant components, thorough rinsing of the joint and reduction. Insertion of a Redon drain.

Depending on the surgical approach to the joint, reattachment of muscle insertions, then wound closure layer by layer.

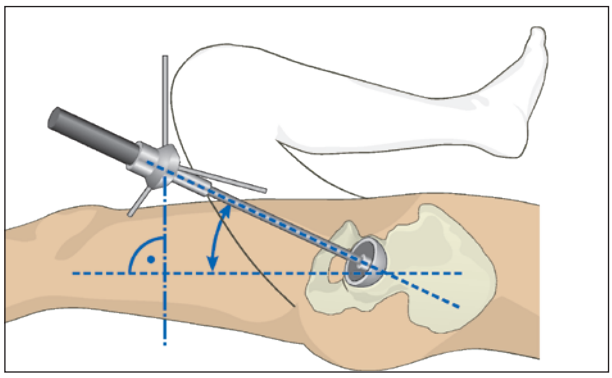


Fig. 19 Inclination of the cup: 40°–50°

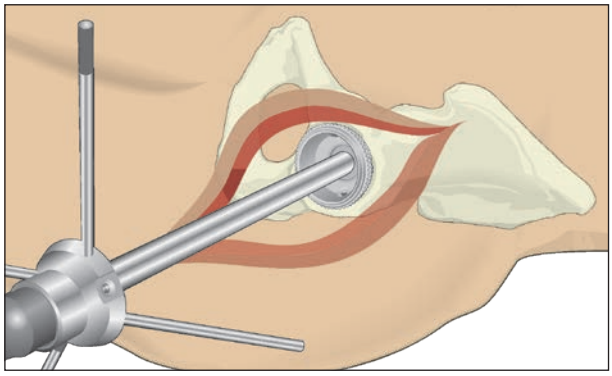


Fig. 20 Anteversion of the cup: 10°–20°

Additional information: Ceramic inlay

Ceramic inlays (ceramys) are only allowed to be used in combination with Mathys ceramic femoral heads.

Remarks

When implanting a ceramic-on-ceramic articulation, always use a trial inlay to perform a trial reduction, and switch to a polyethylene or highly-crosslinked polyethylene inlay if there is any risk of an impingement.

Only use ceramic inlays in new seleXys PC Shells. If any other inlay had been impacted into the shell, no ceramic inlay can be used. A polyethylene inlay must be used in these cases or the cup needs to be revised completely. Ceramic inlays should only be used in acetabular cups that are positioned within the range of 40°–50° of inclination and 10°–20° of anteversion (Figs. 19, 20).

Check range of motion and stability with trial components to avoid rim chipping or postoperative fracture of the implant components.

Manually insert the final ceramic component. Carefully centre the ceramic inlay in the shell prior to final fixation. To avoid complications at the interface between shell and inlay, the inside of the shell must be cleaned, dried and completely undamaged. Palpate and visually check the edge of the shell to ensure that the inlay is not canted before final impaction by a hammer stroke onto the shell impactor.

Removal of the ceramic inlay
Use the extractor if it is necessary to remove a ceramic inlay. Place the extractor in a 90° angle to the cup's face on the outer rim of the cup. The extractor should not contact the inlay during impaction.
Strike the extractor to dislodge the inlay from the cup and remove the inlay.

Remarks
Always check cup stability after having removed the inlay.

Re-use of a removed ceramic inlay is prohibited. In case of fracture of one or both ceramic components, use of a metal head is contraindicated.

In case of persistent pain, trauma or emergence of any noise (e. g. squeaking, clicking), a precise clarification of the problem or cause must be performed.

Removal of the polyethylene inlay
Use a 3.2 or 3.5 mm drill bit to drill a pilot hole into the polyethylene inlay.
Place a 6.5 mm non-self-tapping screw in the drilled hole and tighten it with a screwdriver to lever the polyethylene inlay out of the cup.
In case of an isolated inlay exchange, make sure not to damage the taper on the inner surface of the cup.

Remarks
Do not use self-tapping screws for inlay removal.

Removal of the seleXys PC cup
Ensure full exposure of the acetabular rim before removal of the cup.
Remove cancellous bone screws if present.
Carefully use curved osteotomes or universal cup removal instrument sets to disrupt the implant-bone interface until the cup can be extracted.
For further information about universal cup removal instrument sets contact your local Mathys representative.

4. Handling of seleXys offset impactor (Item no. 58.02.0030)

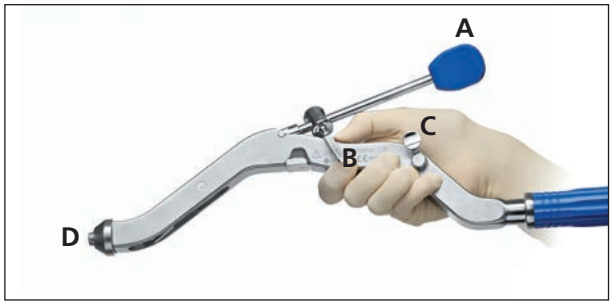


Fig. 21

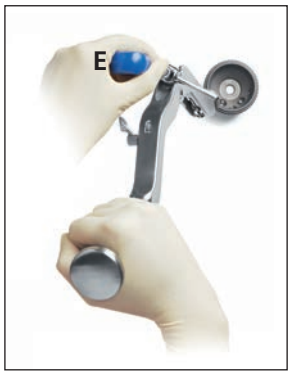


Fig. 22

Fig. 23

Fig. 24

Fig. 25

Preparation of the impactor for assembly of the implant (Fig. 21)
Uphold the lever (A). The ratchet (B) should not be engaged in the matching hole (F). It can be released by pressing the button (C). The front thread must be visible (D).

Fixation of the implant on the impactor (Fig. 22)
Position the threaded part of the Impactor in front of the cup's polar hole.
Screw the Impactor drive chain into the cup by turning the rotating knob (E) clockwise. Do not overtighten.

Introduction of the ratchet (Fig. 23)
Introduce the ratchet (B) into the matching hole (F).

Remarks
Count 1 – 3 clicks after the engagement of the ratchet. The implant must be free to rotate when the handle is turned.

Orientation of the implant (Fig. 24)
Position the screw holes into the desired position by turning the rotating knob (E). Turn clockwise to avoid disengagement of the implant. Push the lever (A) down (firmly) to finally lock the implant.

Insertion of the implant (Fig. 25)
Impact the cup into the acetabulum.

Unlocking the implant (Fig. 25)
After impaction of the implant: press the button (C) on the lower end of the ratchet, the ratchet releases automatically.

Release the implant
Turn the rotating knob (E) counter-clockwise to disengage the instrument from the implant.

Remove the impactor.

5. Implants

seleXys PC Shell

Item no.	Shell size	Number of screw holes
55.41.0042	42 mm	3
55.41.0044	44 mm	3
55.41.0046	46 mm	3
55.41.0048	48 mm	3
55.41.0050	50 mm	5
55.41.0052	52 mm	5
55.41.0054	54 mm	5
55.41.0056	56 mm	5
55.41.0058	58 mm	5
55.41.0060	60 mm	5
55.41.0062	62 mm	5
55.41.0064	64 mm	5

Material seleXys PC shell: Ti6Al7Nb; TiCP coated
Material pole cap and screw hole covers: Ti6Al4V

Cancellous bone screw, sterile

Item no.	Diameter	Length
101.05.57.15.0	5.7 mm	15 mm
101.05.57.20.0	5.7 mm	20 mm
101.05.57.25.0	5.7 mm	25 mm
101.05.57.30.0	5.7 mm	30 mm
101.05.57.35.0	5.7 mm	35 mm
101.05.57.40.0	5.7 mm	40 mm
101.05.57.45.0	5.7 mm	45 mm

Material: Ti6Al4V

seleXys ceramys Inlay *

Item no. 28 mm articulation	Item no. 32 mm articulation	Item no. 36 mm articulation	Shell size	Inlay size
–	–	–	42 mm	AA
55.47.2802	–	–	44 mm	BB
55.47.2803	–	–	46 mm	CC
–	55.47.3204	–	48 mm	DD
–	55.47.3205	–	50 mm	EE
–	55.47.3206	55.47.3606	52 mm	FF
–	–	55.47.3607	54 mm	GG
–	–	55.47.3608	56 mm	HH
–	–	55.47.3609	58 mm	II
–	–	55.47.3610	60 mm	JJ
–	–	55.47.3611	62/64 mm	KK

Material: ZrO_2 – Al_2O_3

** Can only be combined with Mathys ceramic heads.*

seleXys vitamys Inlay, standard

Item no. 28 mm articulation	Item no. 32 mm articulation	Item no. 36 mm articulation	Shell size	Inlay size
52.34.0130	–	–	42 mm	AA
52.34.0131	–	–	44 mm	BB
52.34.0132	–	–	46 mm	CC
52.34.0133	52.34.0150	–	48 mm	DD
52.34.0134	52.34.0151	–	50 mm	EE
52.34.0135	52.34.0152	52.34.0165	52 mm	FF
52.34.0136	–	52.34.0166	54 mm	GG
52.34.0137	–	52.34.0167	56 mm	HH
52.34.0138	–	52.34.0168	58 mm	II
–	–	52.34.0169	60 mm	JJ
–	–	52.34.0170	62/64 mm	KK

Material: vitamys (highly cross-linked UHMWPE, stabilized with vitamin E)

seleXys vitamys Inlay, hooded

Item no. 28 mm articulation	Item no. 32 mm articulation	Item no. 36 mm articulation	Shell size	Inlay size
52.34.0240	–	–	42 mm	AA
52.34.0241	–	–	44 mm	BB
52.34.0242	–	–	46 mm	CC
52.34.0243	52.34.0260	–	48 mm	DD
52.34.0244	52.34.0261	–	50 mm	EE
52.34.0245	52.34.0262	52.34.0275	52 mm	FF
52.34.0246	–	52.34.0276	54 mm	GG
52.34.0247	–	52.34.0277	56 mm	HH
52.34.0248	–	52.34.0278	58 mm	II
–	–	52.34.0279	60 mm	JJ
–	–	–	62/64 mm	KK

Material: vitamys (highly cross-linked UHMWPE, stabilized with vitamin E)

seleXys PE Inlay, standard

Item no. 28 mm articulation	Item no. 32 mm articulation	Shell size	Inlay size
55.43.2801	–	42 mm	AA
55.43.2802	–	44 mm	BB
55.43.2803	–	46 mm	CC
55.43.2804	–	48 mm	DD
55.43.2805	55.43.3205	50 mm	EE
55.43.2806	55.43.3206	52 mm	FF
55.43.2807	55.43.3207	54 mm	GG
55.43.2808	55.43.3208	56 mm	HH
55.43.2809	55.43.3209	58 mm	II
55.43.2810	55.43.3210	60 mm	JJ
55.43.2811	55.43.3211	62/64 mm	KK

Material: UHMWPE

seleXys PE Inlay, hooded

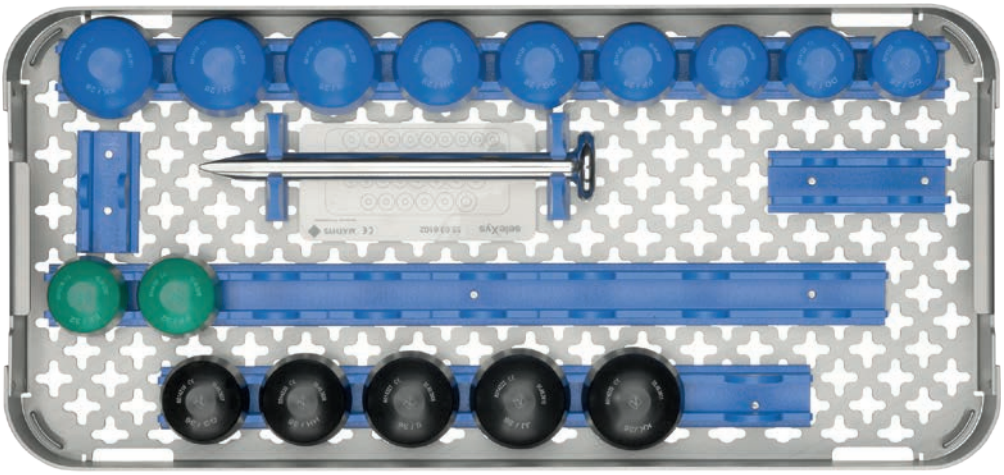
Item no. 28 mm articulation	Item no. 32 mm articulation	Shell size	Inlay size
55.44.2801	–	42 mm	AA
55.44.2802	–	44 mm	BB
55.44.2803	–	46 mm	CC
55.44.2804	–	48 mm	DD
55.44.2805	55.44.3205	50 mm	EE
55.44.2806	55.44.3206	52 mm	FF
55.44.2807	55.44.3207	54 mm	GG
55.44.2808	55.44.3208	56 mm	HH
55.44.2809	55.44.3209	58 mm	II
55.44.2810	55.44.3210	60 mm	JJ
55.44.2811	55.44.3211	62/64 mm	KK

Material: UHMWPE

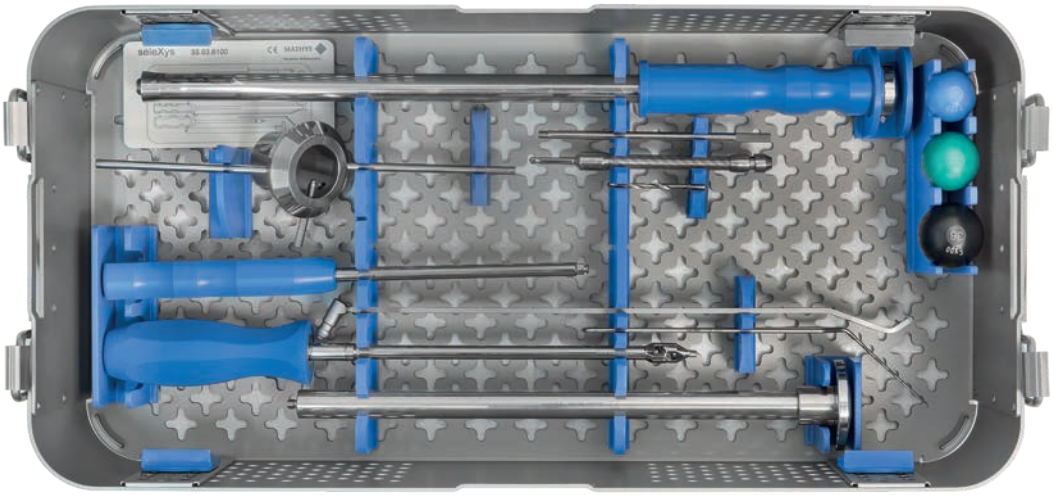
6. Instruments

6.1 seleXys Instrumentation Set

seleXys Instrument Set, Item no. 55.40.0000A



Tray for seleXys Instruments (Insert)

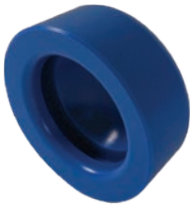


Basic Tray for seleXys Instruments

seleXys Tray, empty

Item no.	Description
55.03.6100	seleXys Tray
55.03.6101	seleXys Lid
55.03.6102	seleXys Insert

Trial Inlay



Item no.	Size	ID	Shell size
55.49.2801	AA	28 mm	42 mm *
55.49.2802	BB	28 mm	44 mm *
55.49.2803	CC	28 mm	46 mm
55.49.2804	DD	28 mm	48 mm
55.49.2805	EE	28 mm	50 mm *
55.49.2806	FF	28 mm	52 mm *
55.49.2807	GG	28 mm	54 mm *
55.49.2808	HH	28 mm	56 mm *
55.49.2809	II	28 mm	58 mm *
55.49.2810	JJ	28 mm	60 mm *
55.49.2811	KK	28 mm	62/64 mm *
55.49.3204	DD	32 mm	48 mm *
55.49.3205	EE	32 mm	50 mm
55.49.3206	FF	32 mm	52 mm
55.49.3207	GG	32 mm	54 mm *
55.49.3208	HH	32 mm	56 mm *
55.49.3209	II	32 mm	58 mm *
55.49.3210	JJ	32 mm	60 mm *
55.49.3211	KK	32 mm	62/64 mm *
55.49.3606	FF	36 mm	52 mm *
55.49.3607	GG	36 mm	54 mm
55.49.3608	HH	36 mm	56 mm
55.49.3609	II	36 mm	58 mm
55.49.3610	JJ	36 mm	60 mm
55.49.3611	KK	36 mm	62/64 mm

** Optional*

Top for Inlay Impactor

Item no.	Diameter
5236.00	28 mm
5235.00	32 mm
5253.00	36 mm

seleXys Shell Post Impactor

Item no.	Diameter
51.34.0019	seleXys Shell Post Impactor *

** Optional*

Instruments

Item no.	
5234.00	Handle for Inlay Impactor

Item no.	
5501.00.2	Drill Bit, 3.2 mm, long

Item no.	
3.14.545	Flexible Shaft

Item no.	
5503.00.3	Drill Guide for 5.7 mm Screws

Item no.	
5504.00.4	Universal Screwdriver

Item no.	
501.04.03.00.1	Positioning Guide

Item no.	
501.04.04.00.1	Cup Impactor

Item no.	Description
501.05.01.00.0	Pole Cap Screwdriver
501.05.01.00.1	Pole Cap Screwdriver, long *

Item no.	
501.06.02.00.0	Extractor for Ceramic Inlays

Item no.	
3.14.045	Depth Gauge

** Optional*

Optional Instruments for MIS

Item no.	
58.02.0030	seleXys Offset Cup Impactor

Item no.	
58.02.0034	Positioning Guide for Offset Cup Impactor

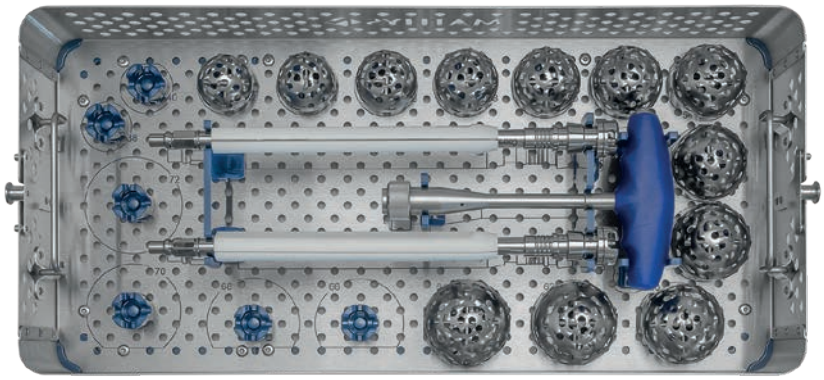
Other Optional Instruments

Item no.	
51.34.0240	Pole Cap Screwdriver Fix

Item no.	
51.34.0241	Pole Cap Screwdriver U-Joint

Item no.	
51.34.0242	Pole Cap Screwdriver Fix/U-Joint

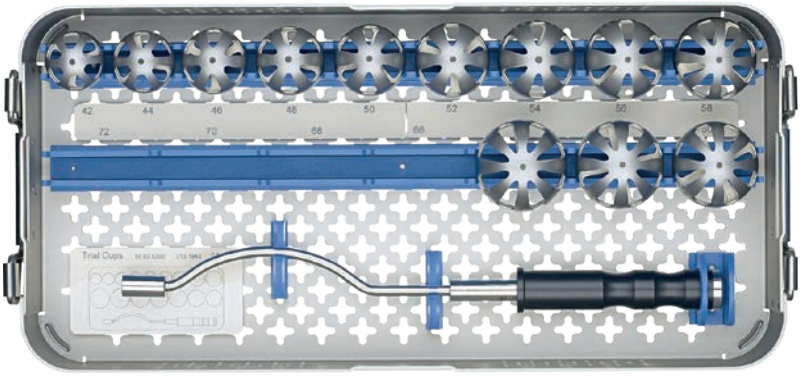
Acetabular Reamers and Trial Cups



Acetabular Reamers

Set no.	Sizes
51.34.1081A	39 – 72 mm

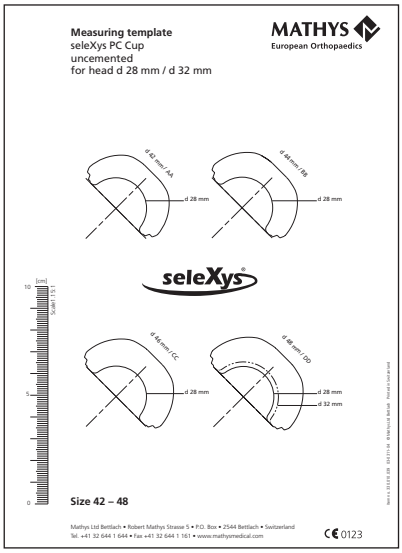
Set no.	
58.02.0000	MIS Reamer Handle



Trial Cups

Set no.	Sizes
55.03.5002A	42 – 72 mm

6.2 Measuring templates



Item no.	
330.010.039	Template seleXys PC Cup

7. Symbols

Manufacturer

Caution

Notes

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