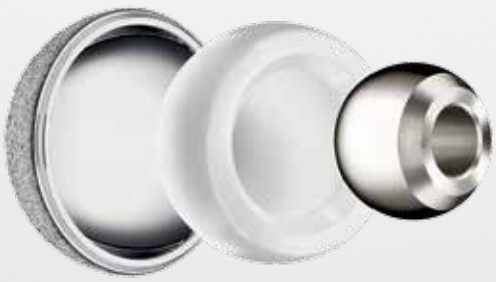
SERENITY®

Surgical technique
SERENITY® Cup



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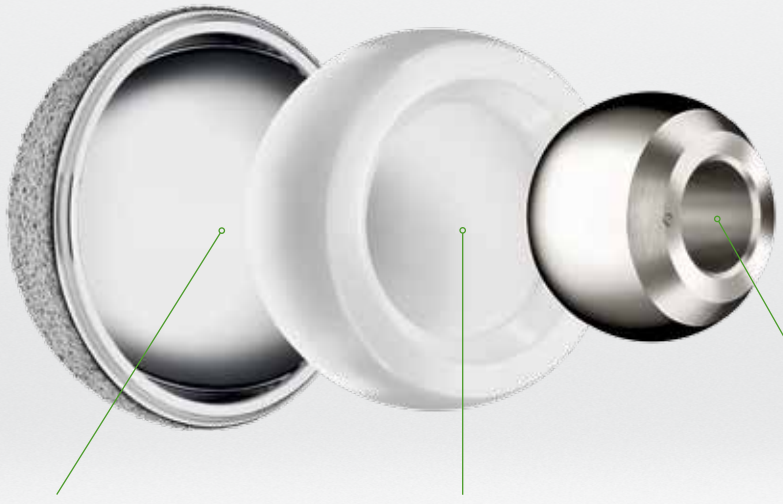
INTRODUCTION

The SERENITY® dual-mobility cup

Concept

The SERENITY® implant is a new-generation dual-mobility cup designed for total hip arthroplasty as first-line or revision treatment in patients with a very high luxation risk.
SERENITY® cup instrumentation is adapted to all surgical approaches and enables surgeons to implant all Symbios® cups. Some parts of the surgical technique described in this document are therefore common to other cup systems (APRIL® and HILOCK).



SERENITY® Cup

Stainless steel cup, interior mirror finish with no hole, coated with porous titanium and hydroxyapatite.

- Equatorial pressfit 1.2 mm in diameter
- Pressfit force proportional to cup diameter
- Anti-luxation equatorial extension with non-invasive design for soft tissues

SERENITY® Insert

Retentive mobile insert in polyethylene (UHMWPE).

- Chamfer designed to limit fretting wear between the neck and the stem

Head

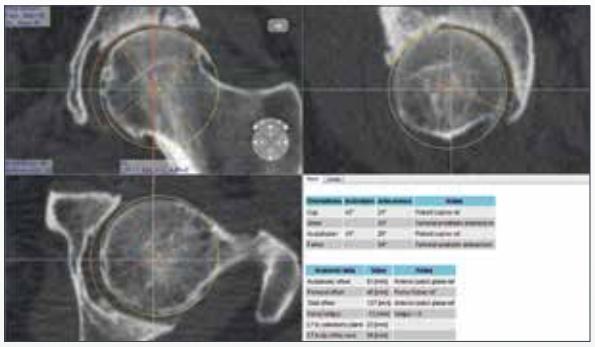
Femoral head selection:

- Material: stainless steel, Cobalt-Chrome, ceramic or ceramic alumina
- Diameter 28 from size 48
- Several offsets available according to the femoral head selected

symbios

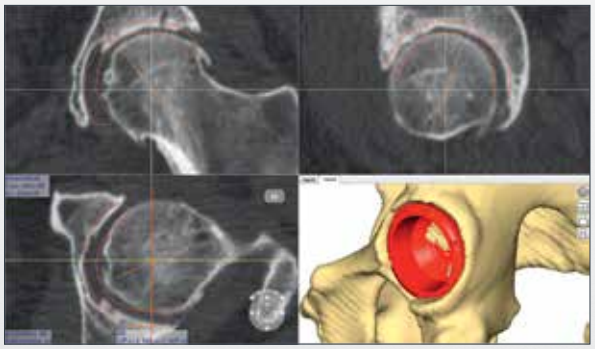
PRE-OPERATIVE PROCESS IN HIP-PLAN®

Analysis of the native acetabular anatomy



- Load patient scan into the software.
- Determine the diameter of the femoral head and the patient's acetabulum.
- Define the anteversion and natural inclination of the acetabulum.

3D cup planning

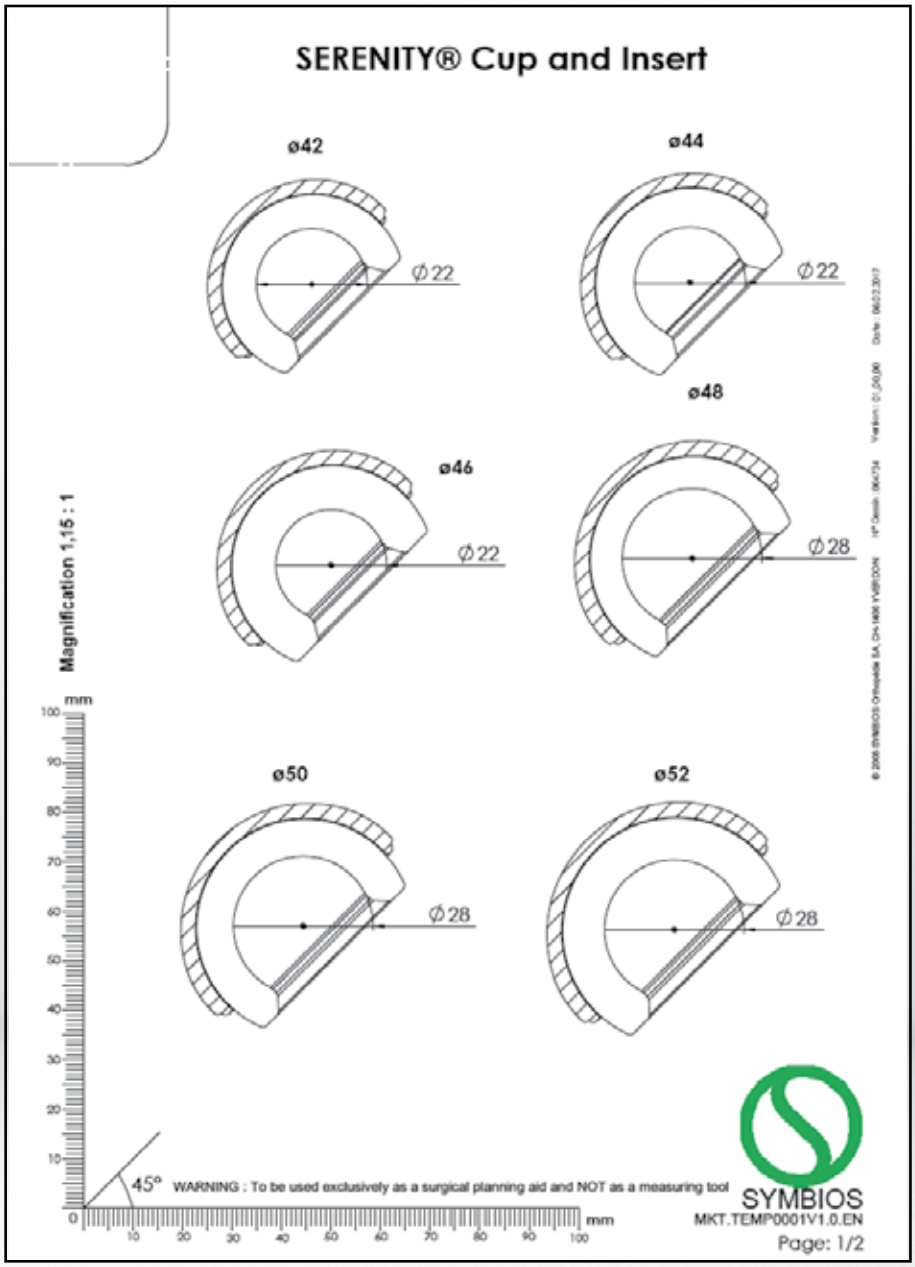


- Determine the precise position of the cup in 3D, as well as its size, inclination and anteversion.
- Examine the implants' functional behavior using the combination of multiplanar views with the surface view of the pelvis, in order to guard against over-sizing which could lead to postoperative conflict with the iliopsoas muscle.

Assessment of final reconstruction

- Estimate the stability of the reconstructed joint (cup and stem) by assessing the impact of the reaming and the position and size of the selected implants.
- Create planning report.

PRE-OPERATIVE PLANNING
2D PLANNING WITH TEMPLATES



- Templates of all SERENITY® cup sizes are provided with a 15% magnification factor.
- The use of templates on front-calibrated images helps determine the size and positioning of the SERENITY® Cup.


symbios
7104 4020
2025101

SURGICAL TECHNIQUE

SURGICAL STEPS

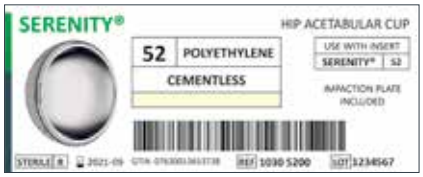
In this surgical technique, some of the steps and instruments are common to the surgical technique for APRIL® and HILOCK cups.

Surgical technique

Appendices

STEP 1
MATERIAL PREPARATION

Implants



X10
SIZES

› **Information :** Single-use impaction plate included in the SERENITY® cup box.

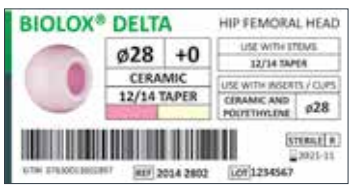
SERENITY® Cup

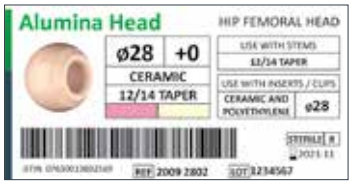
1030 4600	SERENITY® Ø46
1030 4800	SERENITY® Ø48
1030 5000	SERENITY® Ø50
1030 5200	SERENITY® Ø52
1030 5400	SERENITY® Ø54
1030 5600	SERENITY® Ø56
1030 5800	SERENITY® Ø58
1030 6000	SERENITY® Ø60
1030 6200	SERENITY® Ø62
1030 6400	SERENITY® Ø64

X10
SIZES

SERENITY® Insert

1530 4610	SERENITY® Insert Ø46/Ø22.2mm
1530 4820	SERENITY® Insert Ø48/Ø28mm
1530 5020	SERENITY® Insert Ø50/Ø28mm
1530 5220	SERENITY® Insert Ø52/Ø28mm
1530 5420	SERENITY® Insert Ø54/Ø28mm
1530 5620	SERENITY® Insert Ø56/Ø28mm
1530 5820	SERENITY® Insert Ø58/Ø28mm
1530 6020	SERENITY® Insert Ø60/Ø28mm
1530 6220	SERENITY® Insert Ø62/Ø28mm
1530 6420	SERENITY® Insert Ø64/Ø28mm





Compatible SYMBIOS® heads

2010 2201	Cobalt-Chrome Head Ø22.2mm/-2mm
2010 2202	Cobalt-Chrome Head Ø22.2mm/0mm
2010 2801	Cobalt-Chrome Head Ø28mm/-3.5mm
2010 2802	Cobalt-Chrome Head Ø28mm/0mm
2010 2803	Cobalt-Chrome Head Ø28mm/+3.5mm
2011 2801	Stainless Steel Head Ø28mm/-3.5mm
2011 2802	Stainless Steel Head Ø28mm/0mm
2011 2803	Stainless Steel Head Ø28mm/+3.5mm
2014 2801	BIOLOX® Delta Head Ø28mm/-3.5mm
2014 2802	BIOLOX® Delta Head Ø28mm/0mm
2014 2803	BIOLOX® Delta Head Ø28mm/+3.5mm
2009 2801	Alumina Head Ø28mm/-3.5mm
2009 2802	Alumina Head Ø28mm/0mm
2009 2803	Alumina Head Ø28mm/+3.5mm

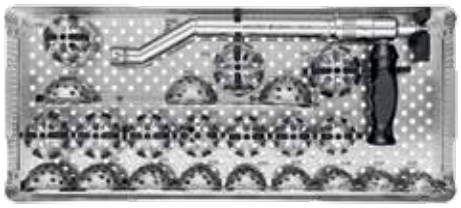
STEP 1
MATERIAL PREPARATION

Instrumentation

7231 0000 Cup Instrumentation

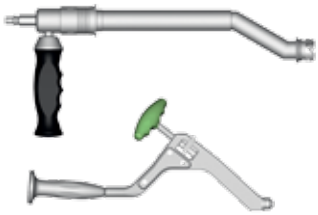
The Cup Instrumentation set is required for completing acetabular preparation preceeding impaction of the SERENITY® Cup.

This set enables surgeons to manage all surgical approaches and to implant alternative Symbios® cup options.

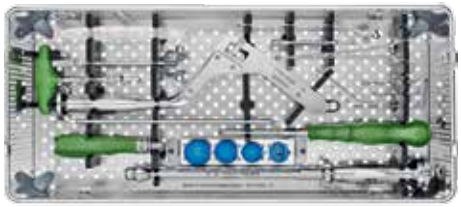


Level 1

Straight instruments



Offset instruments



Level 2

7232 0000 SERENITY® Add-on Instrumentation

SERENITY® Add-on Instrumentation is designed to complement Cup Instrumentation, allowing the SERENITY® insert trials to be used as well as femoral head impaction into insert.

REQUEST FOR SMALL SIZES

SERENITY® Cup

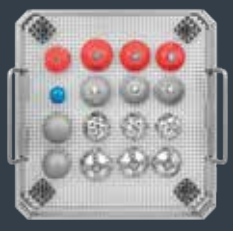
1030 4200	SERENITY® Ø42
1030 4400	SERENITY® Ø44

SERENITY® Insert

1530 4210	SERENITY® Insert Ø42/Ø22.2mm
1530 4410	SERENITY® Insert Ø44/Ø22.2mm

7310 0000 Small Reamers Instrumentation

This instrumentation set is required for implanting previously requested small SERENITY® cup (size 42 or 44). This instrumentation case is delivered with the implants.



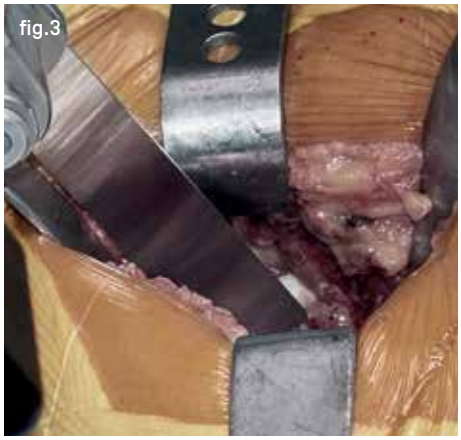
STEP 2
EXPOSURE

2.1. Surgical approach

- Determine the preferred surgical approach. [fig.1]

2.2. Opening of the joint capsule

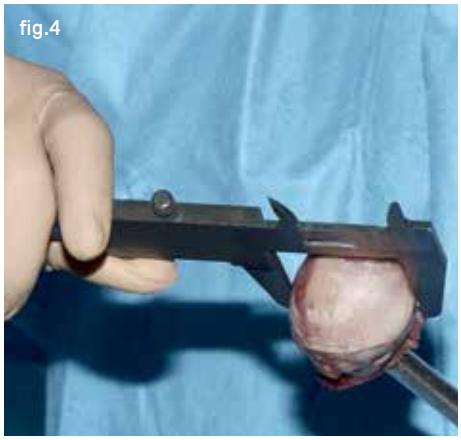
- After opening the joint capsule, remove the soft tissue from around the femoral neck. [fig.2]



2.3. Femoral head resection and extraction

- Carry out a femoral head osteotomy with an oscillating saw referring to the pre-operative plan. [fig.3]
- Extract the femoral head.
- Measure the diameter of the femoral head to best estimate the size of the cup. [fig.4]

› **HIP-PLAN® tip :** The height of the resection can be measured and compared to the height indicated in the pre-operative HIP-PLAN® planning report.



STEP 3
ACETABULAR PREPARATION

3.1. Acetabular preparation

- Perform a complete capsulectomy or extract sufficient capsule to enable reaming.
- Carefully expose the entire acetabulum using appropriately positioned retractors.
- Eliminate all fibrous and cartilaginous tissue as well as osteophytes which could hinder acetabular preparation. **[fig.5]**


fig.5

3.2. Reaming

› **Important :** The reamers are extremely sharp. Pre-assess reamer cutting ability.

- Prepare the acetabulum using acetabulum reamers, beginning with the smallest (42 mm diameter) to find the true floor. **[fig.6]**


fig.6

› **Important :** The recommended inclination for the SERENITY® cup is between 40° and 50°, and the recommended anteversion is between 10° and 20°.

- Progressively increase the diameter of the reamer (in 2 mm increments), taking into account the final anteversion and inclination of the cup, until solid peripheral support is obtained and the subchondral bone begins to bleed. **[fig.7]**

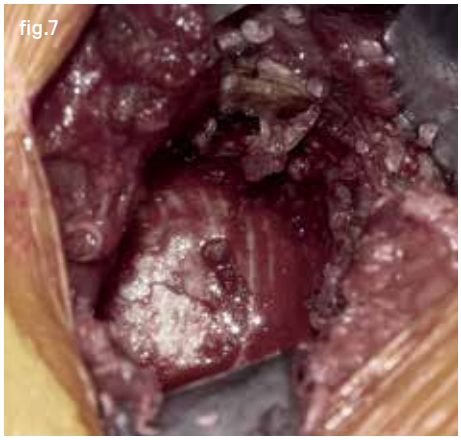


fig.7

› **HIP-PLAN® tip :** Reaming can begin 2 sizes below the size indicated in the pre-operative HIP-PLAN® planning report.

Instruments ^

Straight reamer-handle
7106 2110

or

Offset reamer-handle
7106 2109

Reamer
7102 53xx

STEP 4
CHECKING THE SIZE

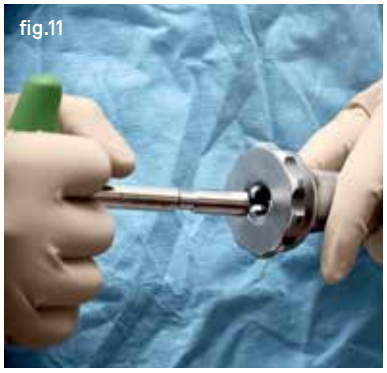
4.1. Impactor assembly

Straight Impactor

- Insert the stem into the body of the straight impactor. [fig.8]

Offset Impactor

- Insert the cardan (threaded from the tip) into the body of the offset impactor. [fig.9]
- Once the cardan is in place, it is blocked by an anti-slip notch system. If this is not the case, push the cardan with your finger. [fig.10]



- Insert the T-handle into the impactor and twist clockwise until it clicks. This locks the thread in the straight impactor [fig.11] or in the cardan of the offset impactor option. [fig.12]

4.2. Trial cup assembly

- Screw the trial cup (sized line to line) onto the impactor. [fig.13]

Instruments ^

Straight impactor
7104 4010

or

Offset impactor
7104 4020

Trial cup
7103 30xx

STEP 4
CHECKING THE SIZE

4.3. Positioning the trial cup

- Release the T-handle by pressing on the button (straight impactor) [fig.14] or simultaneously on both buttons (offset impactor). [fig.15]
- Impact the trial cup into the acetabulum in order to check stability and to validate the size of the chosen definitive cup. [fig.16]
- Check for any cup overhang which might aggrevate soft tissue and optimal orientation. [fig.16]

› **Important :** The trial cup and the definitive SERENITY® implant have differing depths. The trial cup is positioned in the acetabulum to check the sphericity of the reamed bone. Pressfit is not assessed with the trial cup [fig.17]


fig.14


fig.15

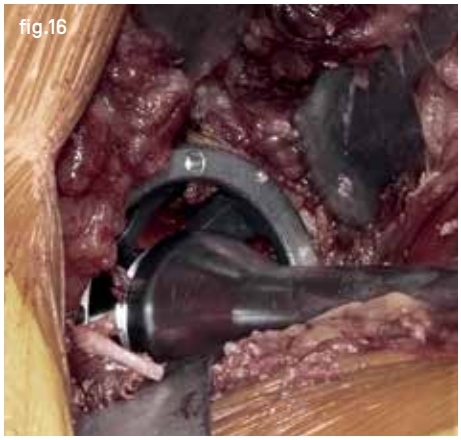
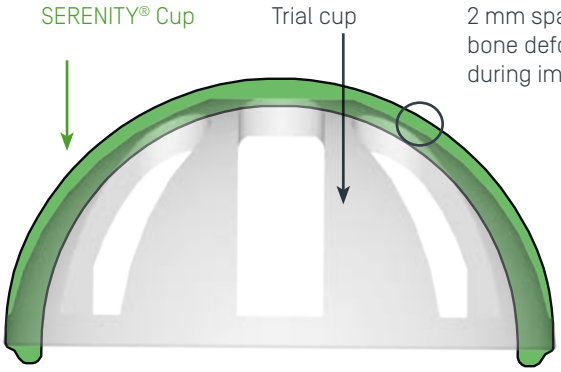


fig.16

fig.17



Instruments ^

Straight impactor
7104 4010

or

Offset impactor
7104 4020

Trial cup
7103 30xx

STEP 5
DEFINITIVE CUP IMPACTION


fig.18


fig.19


fig.20

5.1. Assembly of the SERENITY® adapter onto the impactor

- Confirm the T-handle is in place on the impactor.
- Place the adapter onto the impactor thread.
- Attach the end-cap of the adapter by applying slight pressure and turning the end piece until it fits into the body of the SERENITY® adapter. [fig.18]
- Screw the adapter by turning the body (large diameter) until it connects with the impactor. [fig.19]
- Hold the end-cap of the adapter (small diameter) and turn the T-handle until the end piece engages.

› **Important :** Do not screw more than a single turn as this will prevent the insertion of the impaction plate onto the adapter.

5.2. Mounting the Cup

› **Information :** The impaction plate is matched to cup size. It is sterile, single-use and included in the cup sterile packaging.

- Insert the impaction plate onto the SERENITY® adapter after attaching to the straight or offset impactor. [fig.20]

Instruments ^

Straight impactor
7104 4010

or

Offset impactor
7104 4020

SERENITY® Adapter
7230 3000

SERENITY®
Impaction plate
SE102 4xx

STEP 5
DEFINITIVE CUP IMPACTION

- Screw the T-handle (one turn only) to secure the plate.
- Assemble the SERENITY® Cup onto the single-use plate [fig.21], and lock the assembly with the T-handle until fully tightened.
- Insert the cup into the acetabulum. [fig.22]


fig.21


fig.22

OPTIONAL: CUP REFERENCING GUIDE

- Attach the cup referencing guide to the impactor shaft, just below the handle. [fig.23]
- Screw onto the shaft to fasten the guide.

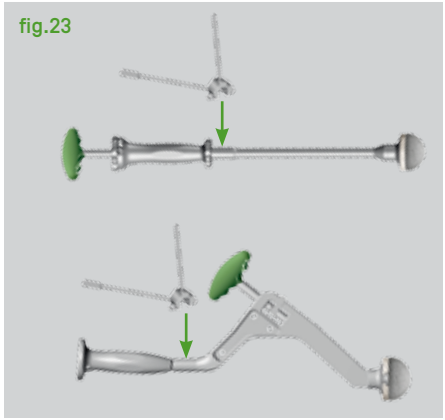


fig.23

Instruments ^

Cup referencing guide
7105 2016

STEP 5
DEFINITIVE CUP IMPACTION


fig.24

5.3. Cup impaction

Impact the cup with a hammer, carefully guiding the cup into the position determined by the pre-operative plan and during reaming. [fig.24]


fig.25

5.4. Removal of the impaction plate

- Unscrew the T-handle and remove the plate-impactor unit. [fig.25]

› **Tip :** If the plate does not detach itself from the cup, tap the impactor lightly with the hammer to separate it from the cup.

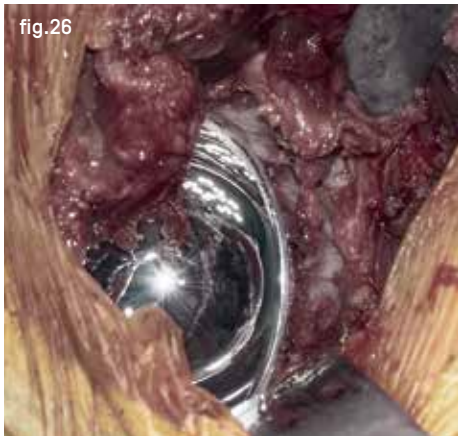


fig.26

5.5. Checking the cup position

› **Information :** The delimitation of the porous-titanium and hydroxyapatite coating indicates the cup's pressfit level.

- Check the position of the cup in relation to the pre-operative plan and for stability through the full range of motion. [fig.26]
- Reposition the cup if necessary.

Instruments ^


Straight impactor
7104 4010

or


Offset impactor
7104 4020


SERENITY® Adapter
7230 3000


SERENITY®
Impaction plate
SE102 4xx

STEP 5
DEFINITIVE CUP IMPACTION

There are two methods of cup repositioning:

1. **Reattach the impaction plate and use the impactor**

   or

2. **Use the specific repositioning end-cap**

- Screw the repositioning end-cap onto the threaded impactor. [fig.27]
- Reposition the cup using the notch on the end-cap and locating the edge of the cup. [fig.28]

fig.27

fig.28

Prepare the femur by referring both to the stem-specific surgical technique and to the pre-operative plan if available.

Instruments ^

Screwable impactor
7004 1000

Repositioner end-cap
7105 2020

SERENITY®
Impaction plate
SE102 4xx

STEP 6
TRIAL REDUCTION

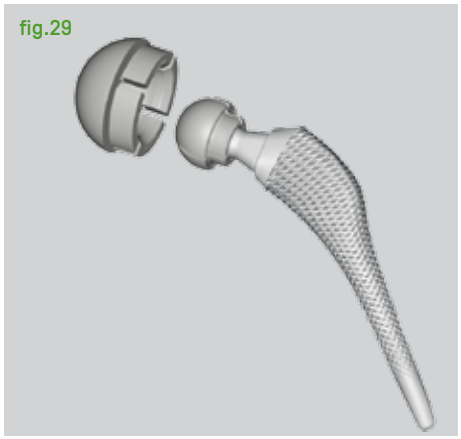


fig.29

6.1. Performing the trial reduction

- After the canal preparation work is complete and the size of the stem has been determined, a trial can be carried out on the trial rasp with a trial neck or directly onto the definitive stem trunion.
- Select the trial head with the desired offset. [fig.29]
- Engage the trial insert onto the trial head. [fig.30]
- Using the head impactor end-cap, perform a reduction of the trial insert into the definitive SERENITY® Cup. [fig.31]
- Assess for function check joint mobility and stability and change the trial head offset if necessary.

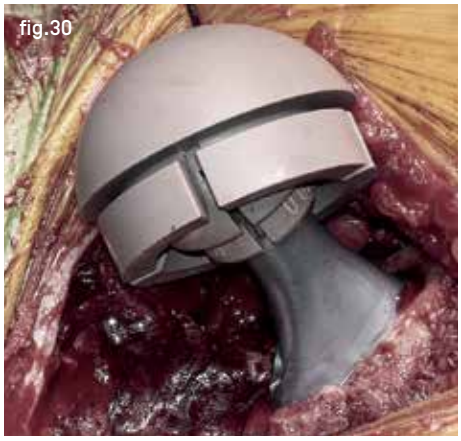


fig.30

6.2. Extraction of trial implants

- Hold the trial insert in place and lever by luxating the hip, which will enable the disassembly of the trial head and trial insert.
- Next, remove the trial head.

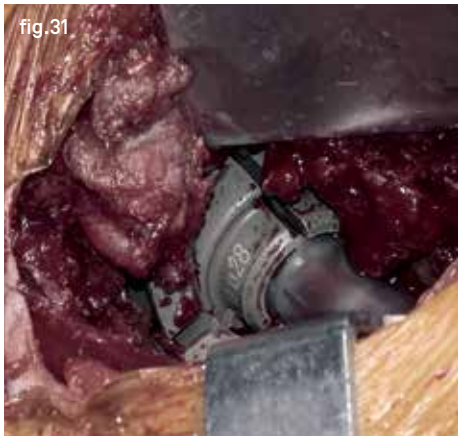


fig.31

› **Tip :** If the insert is extracted with the head still in place, use a trial neck as a lever to remove the trial head from the insert.

Instruments ^

Trial head
7003 4xxx

SERENITY® Trial insert
7230 2xxx

STEP 7
FEMORAL HEAD IMPACTION INTO INSERT

7.1. Assembling the press

- Assemble the fork of the press onto the body by pressing the 2 buttons on each side. [fig.32]
- Screw the insert base onto the press body. [fig.33]
- Screw the handle onto the fork of the press. [fig.34]
- Place the 12/14 end-cap in the fork of the press. [fig.35]
- Give the end-cap a quarter turn to lock it (black horizontal lines). [fig.36]


fig.32


fig.33


fig.34


fig.35

fig.36

Instruments

SERENITY® Press
7230 1000

12/14 End-cap
PR102 011

STEP 7
FEMORAL HEAD IMPACTION INTO INSERT


fig.37

7.2. Femoral head impaction

- Hold the press in «open» position, placing the insert base as far away from the end-cap as possible.
- Insert the femoral head onto the end-cap.
- While holding the press in «open» position, place the insert by centering it onto the femoral head, then press the base against the insert. [fig.37]


fig.38

- Apply pressure using the trigger of the press. You hear the distinctive noise of air escaping when the head impaction has been completed correctly. [fig.38]

› **Tip :** To make impaction easier, you can lubricate the trial insert with sterile water.

Instruments ^

SERENITY® Press
7230 1000

STEP 7
FEMORAL HEAD IMPACTION INTO INSERT

CUP REVISION WHILE KEEPING STEM IN PLACE

- Select the end-cap specific to the stem neck trunion:
  10/12 End-cap: Impaction of a 10/12 femoral head on a femoral stem with 10/12 trunion
  12/14 End-cap: Impaction of a 12/14 femoral head on a femoral stem with 12/14 trunion
- Insert the selected end-cap into the press fork as described in section 7.1 of this surgical technique.
- Impact the head onto the insert as described in section 7.2 of this surgical technique.

12/14 End-cap
PR102 011

10/12 End-cap
PR102 010

CUP REVISION KEEPING STEM/HEAD UNIT IN PLACE

- Clip the internal end-cap in the press fork.
- Place the internal end-cap around the stem trunion behind the femoral head.
- Place the insert on the femoral head while centering it, then press the base against the insert.
- Apply pressure using the trigger of the press. You hear the distinctive noise of air escaping when the head impaction has been completed correctly.

Internal end-cap
PR100 018

Instruments ^

SERENITY® Press
7230 1000

12/14 End-cap
PR102 011

12/14 End-cap
PR102 010

Internal end-cap
PR100 018

STEP 8
FINAL REDUCTION


fig.39

8.1. Final reduction

- Insert the head-insert unit onto the stem trunion.
- Impact the head onto the stem by using the head impactor end-cap, positioned on the insert.
- Perform final implant reduction with the head impactor end-cap. [fig.39]
- Conduct joint function and stability tests with all the definitive implants in situ.


fig.40

8.2. Closure

- Close the joint and the wound following standard procedure. [fig.40]

APPENDICES

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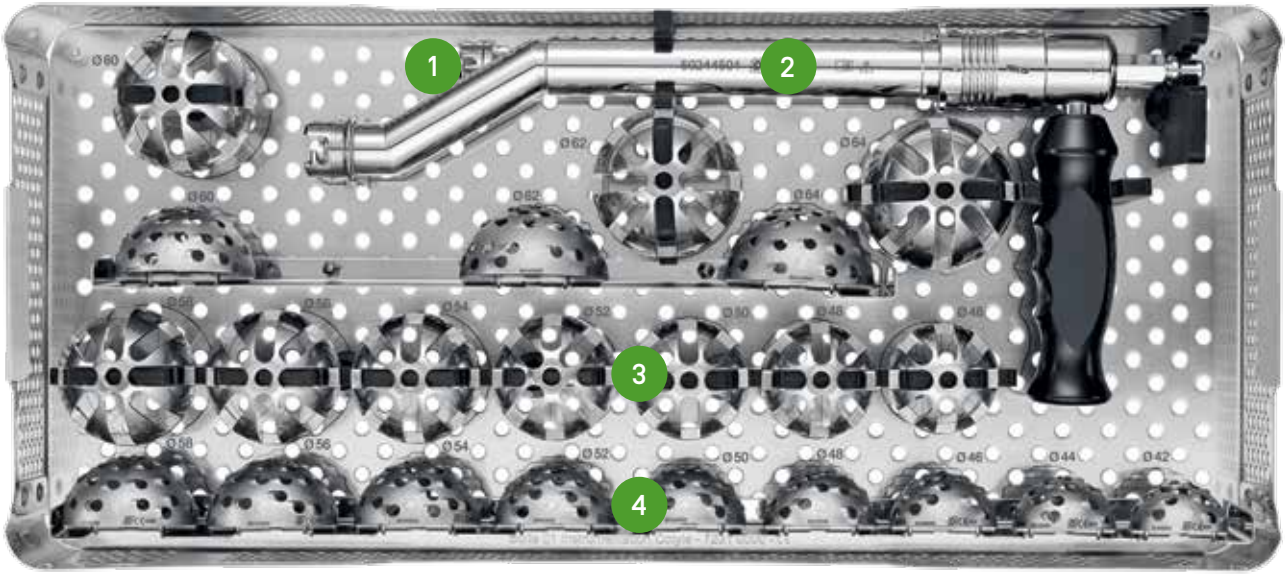
APPENDIX 1
INSTRUMENT REFERENCES

symbios

Cup Instrumentation

REF 7231 0000



Level 1

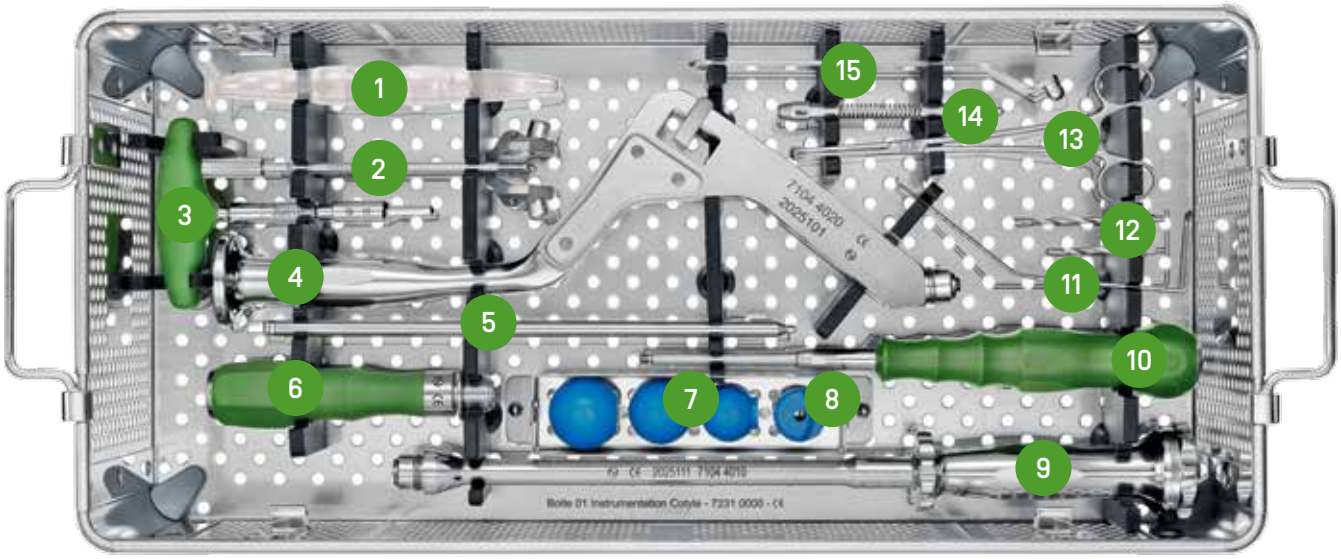
	Description	Reference	Quantity
1	Straight reamer-handle	7106 2110	1
2	Offset reamer-handle	7106 2109	1
3	Trial cup Ø46	7103 3046	1
	Trial cup Ø48	7103 3048	1
	Trial cup Ø50	7103 3050	1
	Trial cup Ø52	7103 3052	1
	Trial cup Ø54	7103 3054	1
	Trial cup Ø56	7103 3056	1
	Trial cup Ø58	7103 3058	1
	Trial cup Ø60	7103 3060	1
	Trial cup Ø62	7103 3062	1
	Trial cup Ø64	7103 3064	1

	Description	Reference	Quantity
4	Reamer Ø42	7102 5342	1
	Reamer Ø44	7102 5344	1
	Reamer Ø46	7102 5346	1
	Reamer Ø48	7102 5348	1
	Reamer Ø50	7102 5350	1
	Reamer Ø52	7102 5352	1
	Reamer Ø54	7102 5354	1
	Reamer Ø56	7102 5356	1
	Reamer Ø58	7102 5358	1
	Reamer Ø60	7102 5360	1
	Reamer Ø62	7102 5362	1
	Reamer Ø64	7102 5364	1

APPENDIX 1
INSTRUMENT REFERENCES

Cup Instrumentation

REF 7231 0000



Level 2

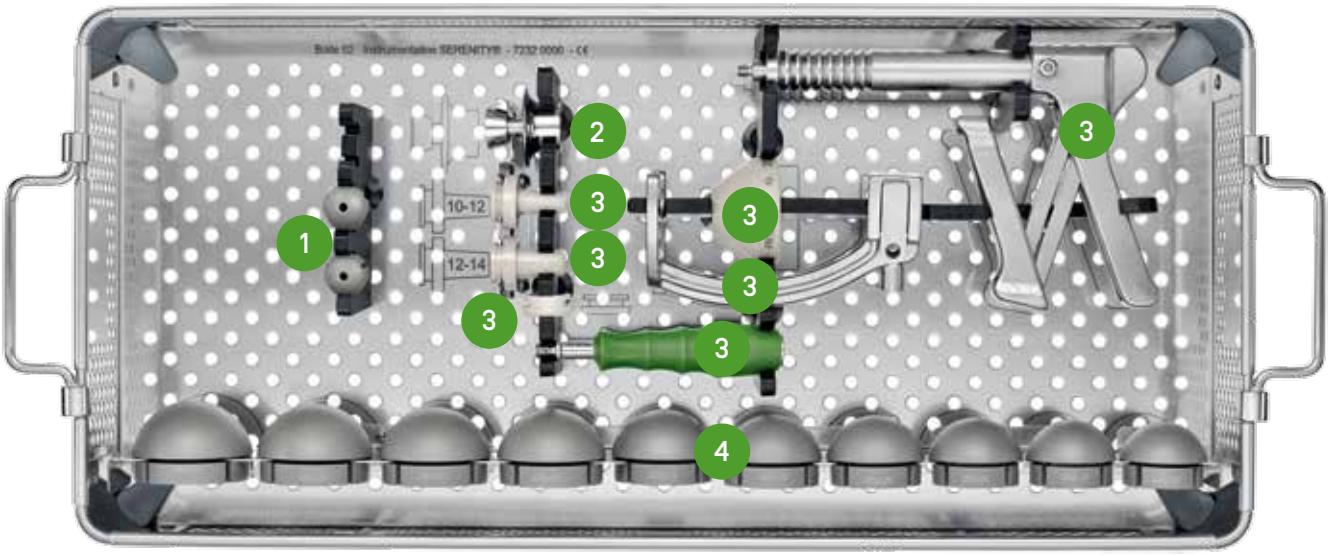
	Description	Reference	Quantity
1	Suction cup for Ceramic Insert	7104 4002	1
2	Cup referencing guide	7105 2016	1
3	T-handle	PR100 011	1
4	Offset cup impactor	7104 4020	1
5	Cardan-shaft hex screwdriver end-cap	7104 6002	1
	Straight hex screwdriver end-cap	7104 6001	1
6	Universal handle	7105 5000	1
7	Insert impaction end-cap Ø28	7104 2028	1
	Insert impaction end-cap Ø32	7104 2032	1
	Insert impaction end-cap Ø36	7104 2036	1
8	Repositioner end-cap	7105 2020	1
9	Straight cup impactor	7104 4010	1
10	Screwable impactor	7004 1000	1
11	Measurer	7105 3001	1
12	Drill bit Ø3.2 mm x 40 mm	7102 4001	2
	Drill bit Ø3.2 mm x 60 mm	7102 4002	2
13	Screw holder	7104 7004	1
14	Flexible shaft	7104 6010	2
15	Drill guide Ø3.2 mm	7105 1006	1

APPENDIX 1
INSTRUMENT REFERENCES

symbios

SERENITY® Add-On Instrumentation

REF 7232 0000



	Description	Reference	Quantity
1	Trial head Ø22.2mm/-2mm	7003 4122	1
	Trial head Ø22.2mm/0mm	7003 4222	1
2	SERENITY® Adapter	7230 3000	1
3	SERENITY® Press	7230 1000	1
4	SERENITY® Trial insert Ø46	7230 2246	1
	SERENITY® Trial insert Ø48	7230 2848	1
	SERENITY® Trial insert Ø50	7230 2850	1
	SERENITY® Trial insert Ø52	7230 2852	1
	SERENITY® Trial insert Ø54	7230 2854	1
	SERENITY® Trial insert Ø56	7230 2856	1
	SERENITY® Trial insert Ø58	7230 2858	1
	SERENITY® Trial insert Ø60	7230 2860	1
	SERENITY® Trial insert Ø62	7230 2862	1
	SERENITY® Trial insert Ø64	7230 2864	1

APPENDIX 2
IMPLANT REFERENCES

SERENITY®

Dual-mobility pressfit cementless cup.
Stainless steel (M30NW-ISO 5832-9), porous titanium and hydroxyapatite coating.

Sizes	Ref.	Head compatibility	
		Ø22.2	**Ø28**
42*	1030 4200*	•	
44*	1030 4400*	•	
46	1030 4600	•	
48	1030 4800		•
50	1030 5000		•
52	1030 5200		•
54	1030 5400		•
56	1030 5600		•
58	1030 5800		•
60	1030 6000		•
62	1030 6200		•
64	1030 6400		•

SERENITY® Insert

Retentive Mobile insert. Polyethylene (UHMWPE, ISO 5834-2).

Cup sizes	**Ø22.2**	**Ø28**
42*	1530 4210*	
44*	1530 4410*	
46	1530 4610	
48		1530 4820
50		1530 5020
52		1530 5220
54		1530 5420
56		1530 5620
58		1530 5820
60		1530 6020
62		1530 6220
64		1530 6420

Alumina Head

Ceramic alumina head (Al203-ISO 6474-1), compatible with 12/14 5°40' taper.

SIzes	Offset in mm		
	-3.5	**+0**	**+3.5**
ø28	2009 2801	2009 2802	2009 2803**

BIOLOX® Delta Head

Ceramic head (Al203+Zr02-ISO 6474-2), compatible with 12/14 5°40' taper.

Sizes	Offset in mm		
	-3.5	**+0**	**+3.5**
ø28	2014 2801	2014 2802	2014 2803**

Cobalt-Chrome Head

Cobalt-Chrome Head (CrCoMo-ISO 5832-12), compatible with 12/14 5°40' taper.

Sizes	Offset in mm			
	-3.5	**-2**	**+0**	**+3.5**
ø22.2	-	2010 2201	2010 2202	-
ø28	2010 2801	-	2010 2802	2010 2803**

Stainless Steel Head

Stainless steel head (ISO 5832-9), compatible with 12/14 5°40' taper.

Sizes	Offset in mm		
	-3.5	**+0**	**+3.5**
ø28	2011 2801	2011 2802	2011 2803**

* Available by order only

**Not recommended for use with Symbios® CUSTOM HIP™ stems and SPS® HA

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