SERENITY®

Surgical technique
SERENITY® Cemented

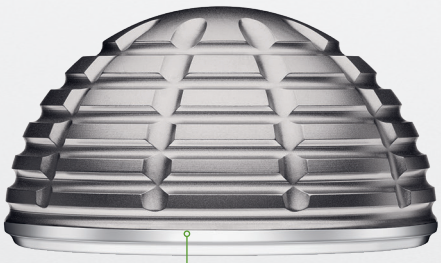
symbios
custom-made for you

INTRODUCTION

The SERENITY® dual-mobility system

Concept

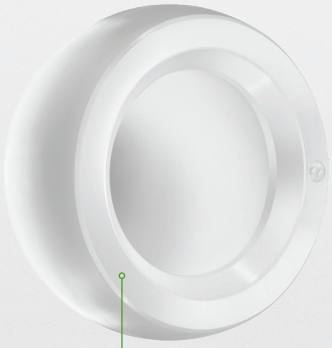
SERENITY® Cemented is a new-generation dual-mobility cup designed for total hip arthroplasty as primary or revision treatment in patients with a very high luxation risk.
SERENITY® cup instrumentation is adapted to all surgical approaches and enables surgeons to implant all Symbios® cups. Some parts of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



SERENITY® Cemented Cup

Stainless steel cup, interior mirror finish.

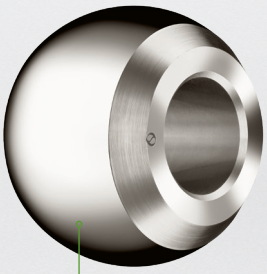
- Horizontal and vertical grooves to increase contact between implant and cement
- Anti-luxation equatorial extension with non-invasive design for soft tissues



SERENITY® Insert

Retentive mobile insert in polyethylene (UHMWPE).

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



Head

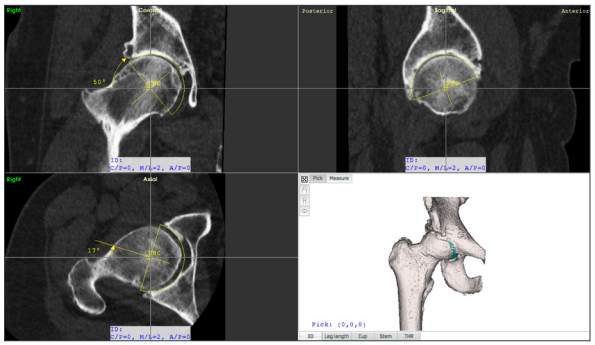
Femoral head selection :

- Material : stainless steel, cobalt-chrome, ceramic
- Diameter 28 from cup size 48
- Several offsets available according to the femoral head selected

symbios

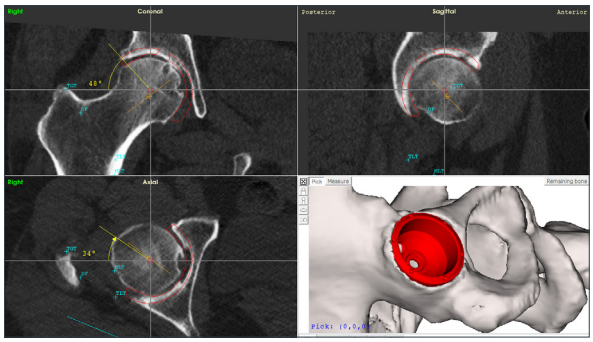
PRE-OPERATIVE PROCESS IN HIP-PLAN®

Analysis of the native anatomy



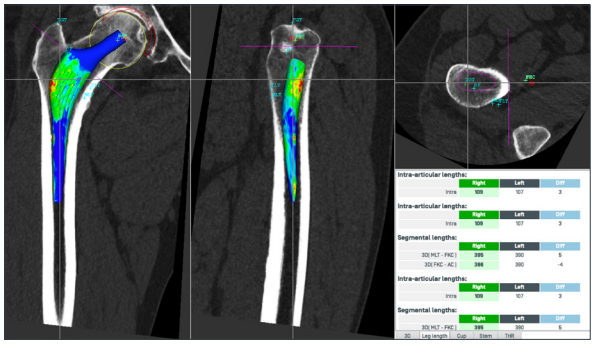
- Load patient scan into the software.
- Determine the femoral head and acetabular diameter of the patient.
- Determine the native acetabular anteversion and inclination.

3D-planning of the cup



- Precisely determine in 3 dimensions the positioning of the cup, as well as its size, inclination and anteversion.
- Examine the functional behaviour of implants thanks to the combination of multi-plan views together with the surface view of the pelvis. Evaluate eventual cup oversizing which can lead to conflict with the iliopsoas muscle during flexion and extension of the prosthetic joint.

Evaluation of the final reconstruction



- Estimate the stability of the reconstructed joint (cup and stem) by evaluating the functional outcome of reaming, position and size of chosen implants.
- Generate the planning report file.

SURGICAL TECHNIQUE

SURGICAL STEPS

In this surgical technique, some of the steps and instruments are common to the surgical technique of other cup systems.

Surgical technique

Appendices

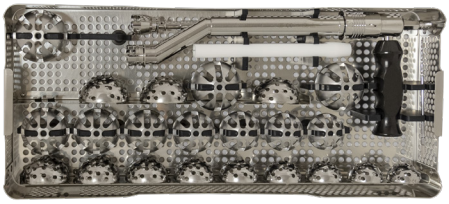
STEP 1
MATERIAL PREPARATION

Instrumentation

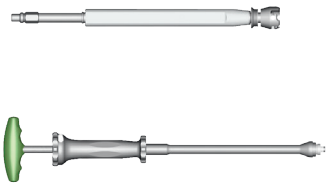
7231 1000 Cup Instrumentation

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

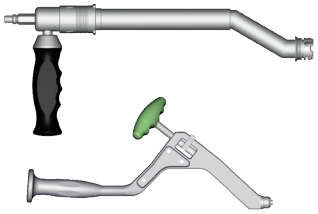
This set enables surgeons to manage all surgical approaches and to implant alternative Symbios® cup options.



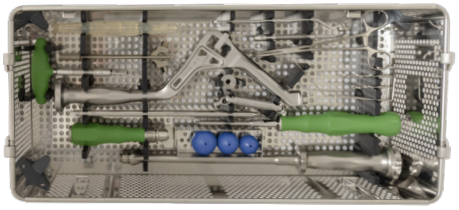
Level 1



Straight instruments



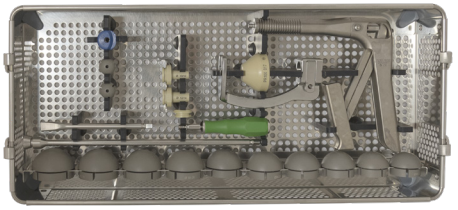
Offset instruments



Level 2

7232 1000 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® Cemented Cup

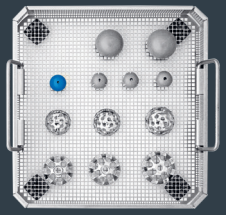
1031 4200	SERENITY® Cemented Ø42
1031 4400	SERENITY® Cemented Ø44

SERENITY® Insert

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

7310 0000 Small Reamers Instrumentation

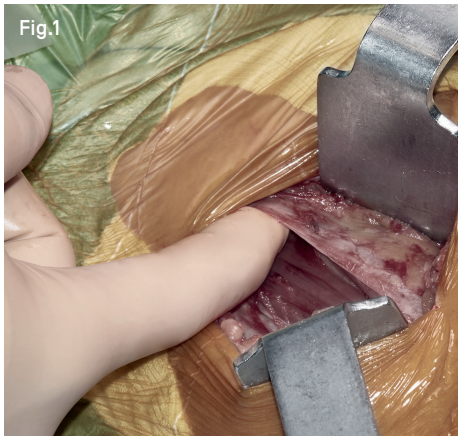
This instrumentation set is required for implanting previously requested small SERENITY® cup (size 42 or 44). This instrumentation case is delivered with the implants.



STEP 2
EXPOSURE

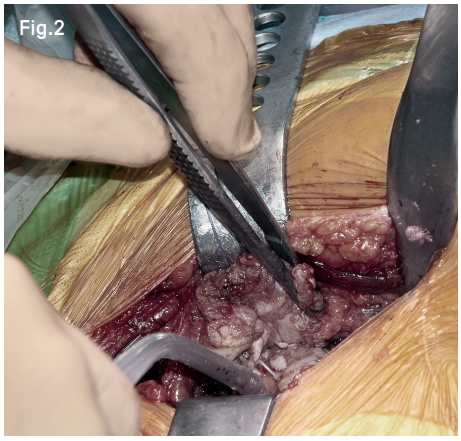
2.1. Surgical approach

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



2.2. Opening of the joint capsule

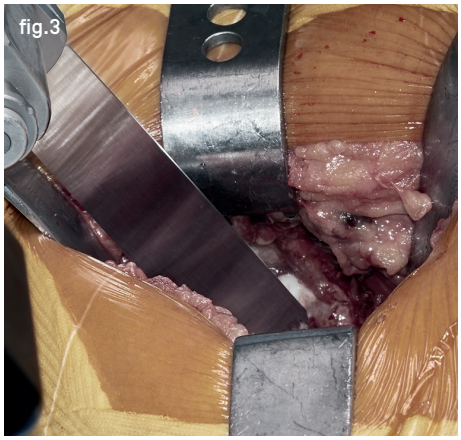
- After opening the joint capsule, remove the soft tissue from around the femoral neck. [Fig.2]

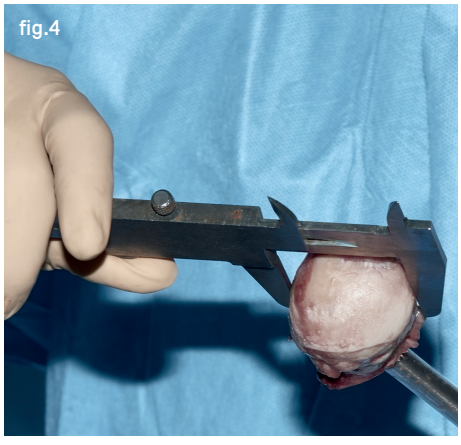


2.3. Femoral head resection and extraction

- 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

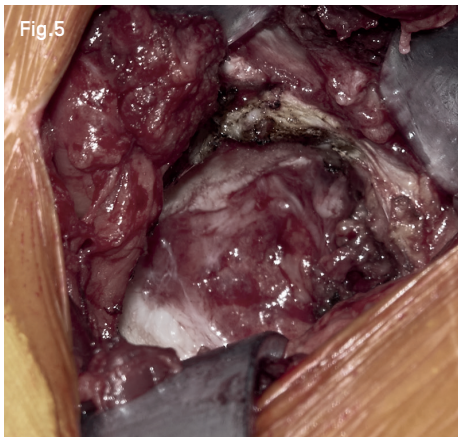


Fig.5

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]

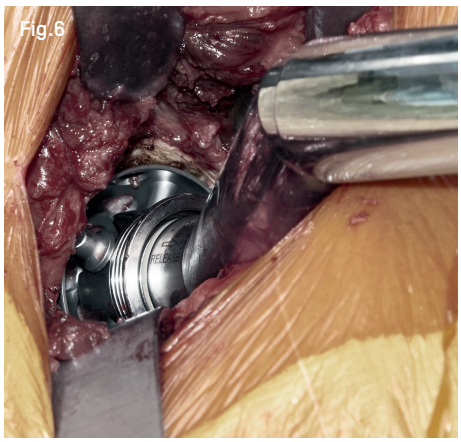


Fig.6

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]

› **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]

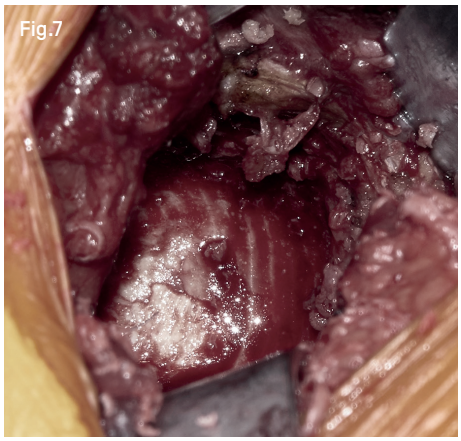


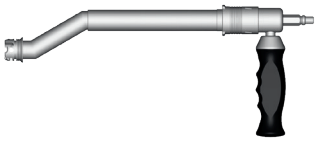
Fig.7

› **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 54xx

STEP 4
CHECKING THE SIZE

4.1. Impactor assembly

Straight Impactor

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

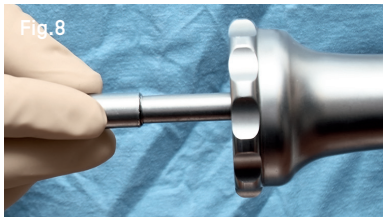


Fig.8

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]

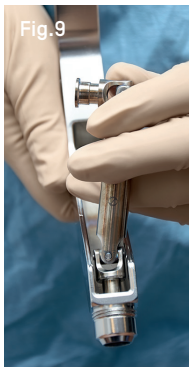


Fig.9

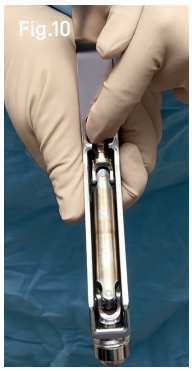


Fig.10

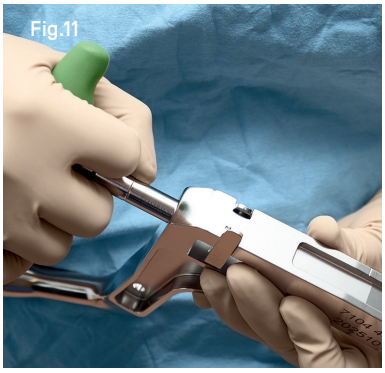


Fig.11

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

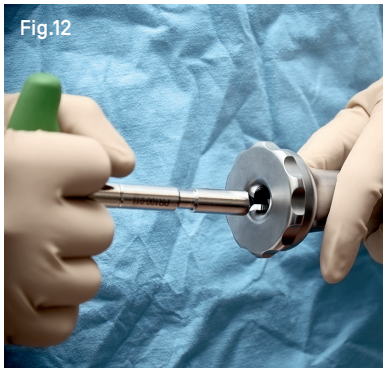


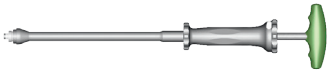
Fig.12

4.2. Trial cup assembly

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

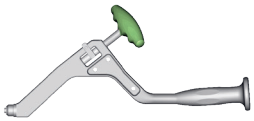

Fig.13

Instruments



Straight impactor
7104 401x

or



Offset impactor
7104 40x0

Trial cup
7103 30xx

STEP 4
CHECKING THE SIZE

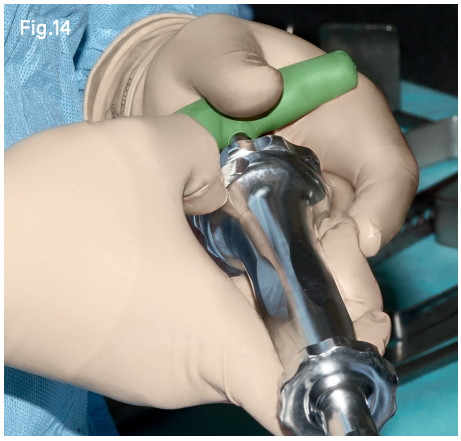


Fig.14


Fig.15

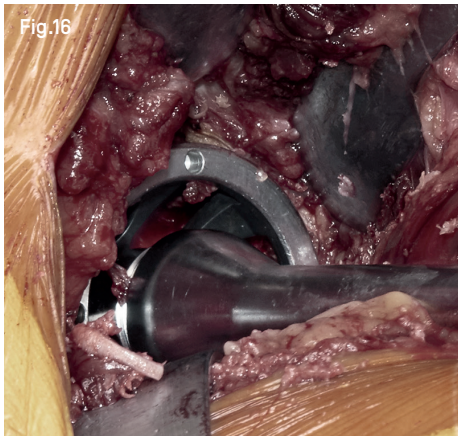


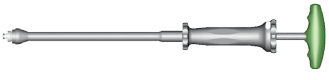
Fig.16

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]

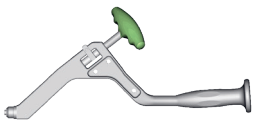
› **Important:** For the SERENITY® Cemented cup, please observe that a certain cement mantle thickness is required.

Instruments ^



Straight impactor
7104 401x

or



Offset impactor
7104 40x0

Trial cup
7103 30xx

STEP 5
DEFINITIVE CUP IMPACTION

SERENITY® CEMENTED CUP

5.1. Cup implantation

- Assemble the SERENITY® impaction plate onto the SERENITY® gripper priorly assembled with the universal handle.

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

- Wash and dry the acetabulum before applying the cement. Prepare the cement mixture in accordance with the manufacturer's instructions.
- Apply cement into the reamed acetabulum.
- Carefully position the cup into the position determined by the pre-operative plan and during reaming using the impaction plate assembled with the gripper. **(Fig.17)**
- Once implant position has been controlled, maintain the implant until cement hardens. **(Fig.18)**
- Remove the gripper and the impaction plate once cement polymerization is complete.

› **Information :** To select the final SERENITY® Cemented cup size, it is recommended to choose a cup size smaller than the trial cup to allow a minimal cement mantle around the implant.

⚠ **CAUTION :** Make sure that all the cement present on the rim and in the SERENITY® Cemented cup is completely removed. Extreme caution must be taken to avoid damaging the cement.

Fig.17

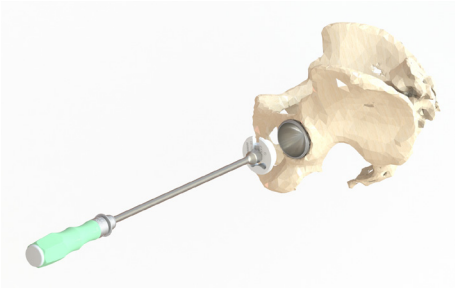
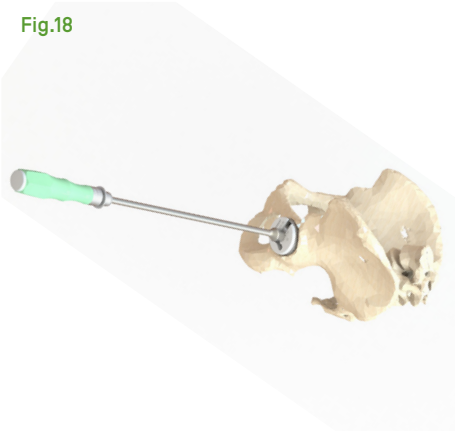


Fig.18



Instruments ^

SERENITY®
Impaction plate II
SE103 4xx

SERENITY® Gripper
7230 1002

Universal handle
7105 5000

STEP 5
DEFINITIVE CUP IMPACTION

SERENITY® CEMENTED CUP WITH AN ACETABULAR RECONSTRUCTION CAGE

5.2. Reconstruction cage positioning

- In case of larger acetabular defect, the SERENITY® Cemented can be used with an acetabular reconstruction cage.
- Ensure to carefully read the manufacturer's instructions for use and surgical technique of the chosen acetabular reconstruction cage.
- Ensure to identify relevant features for the suitability assessment of the combination with the SERENITY® Cemented cup (reaming diameter, cement thickness, component size). [Fig.19]

Fig.19

External diameter of the cage	Associated cups diameter
Ø 50 mm	Ø 42-44 mm
Ø 54 mm	Ø 46-48 mm
Ø 58 mm	Ø 50-52 mm
Ø 62 mm	Ø 54-56 mm
Ø 64 mm	Ø 58-60 mm

5.3. Cup implantation

- Prepare the cement mixture in accordance with the manufacturer's instructions.
- Apply cement into the acetabular reconstruction cage.
- Position the cup in the reconstruction cage using the impaction plate assembled with the gripper. [Fig.17]
- Once implant position has been controlled, pressurise the implant until cement hardens. [Fig.18]

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

Instruments ^

SERENITY®
Impaction plate II
SE103 4xx

SERENITY® Gripper
7230 1002

Universal handle
7105 5000

STEP 6
TRIAL REDUCTION

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.20)**
- Engage the trial insert onto the trial head. **(Fig.21)**
- Using the head impactor end-cap, perform a reduction of the trial insert into the definitive SERENITY® Cemented cup. **(Fig.22)**
- Assess for function check joint mobility and stability and change the trial head offset if necessary.

Fig.20

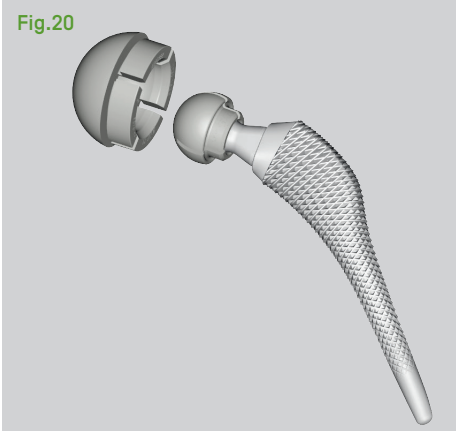
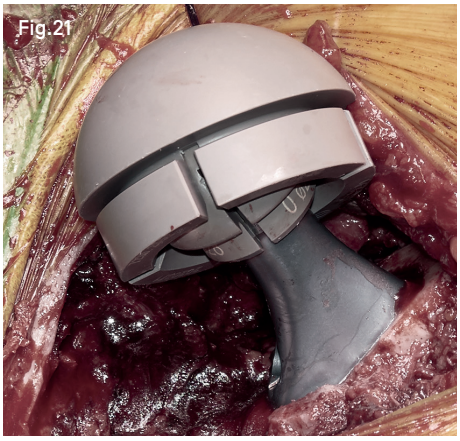


Fig.21



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.

› **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.

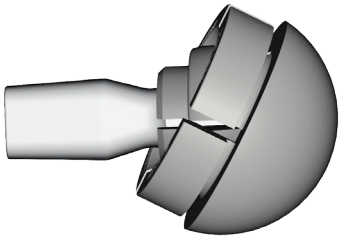
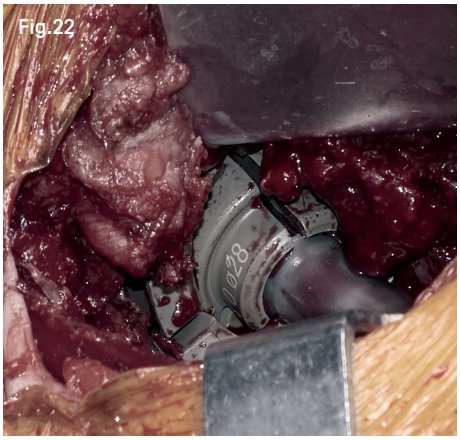


Fig.22



Instruments ^

Trial head
7003 4xxx

SERENITY® Trial insert
7230 2xxx

STEP 7
FEMORAL HEAD IMPACTION INTO INSERT

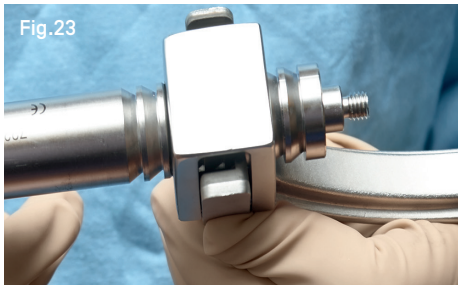


Fig.23

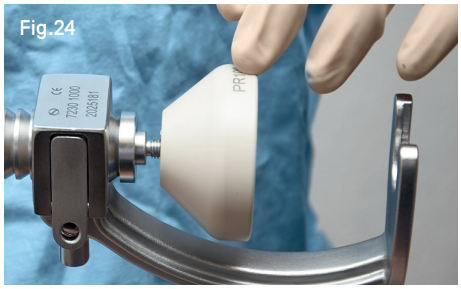


Fig.24

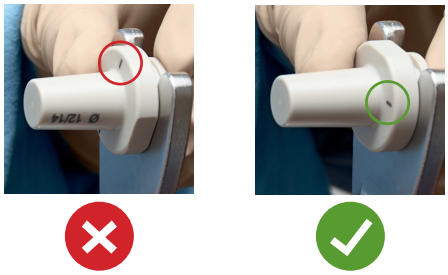

Fig.25


Fig.26

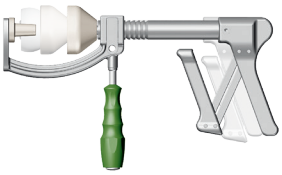
7.1. Assembling the press

- Assemble the fork of the press onto the body by pressing the 2 buttons on each side. [Fig.23]
- Screw the insert base onto the press body. [Fig.24]
- Screw the handle onto the fork of the press. [Fig.25]
- Place the 12/14 end-cap in the fork of the press. [Fig.26]
- Give the end-cap a quarter turn to lock it (black horizontal lines). [Fig.27]

Fig.27



Instruments



SERENITY® Press
7230 1000

12/14 End-cap
PR102 011

STEP 7
FEMORAL HEAD IMPACTION INTO INSERT

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.28]**

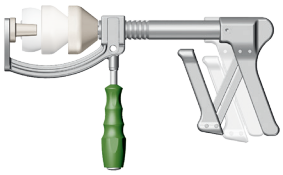

Fig.28

- Apply pressure using the trigger of the press. A distinctive noise of air escaping is heard when the head-insert assembly has been completed correctly. **[Fig.29]**


Fig.29

› **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.
- Impact the head onto the insert as described in section 7.2.

12/14 End-cap
PR102 011

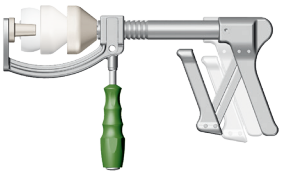
10/12 End-cap
PR102 010

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

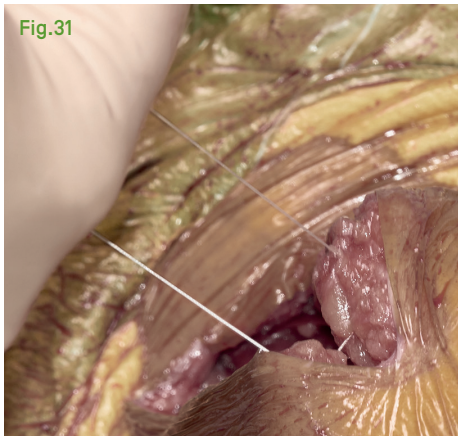
STEP 8
FINAL REDUCTION

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.30]
- Conduct joint function and stability tests with all the definitive implants in situ.

8.2. Closure

- Close the joint and the wound following standard procedure. [Fig.31]

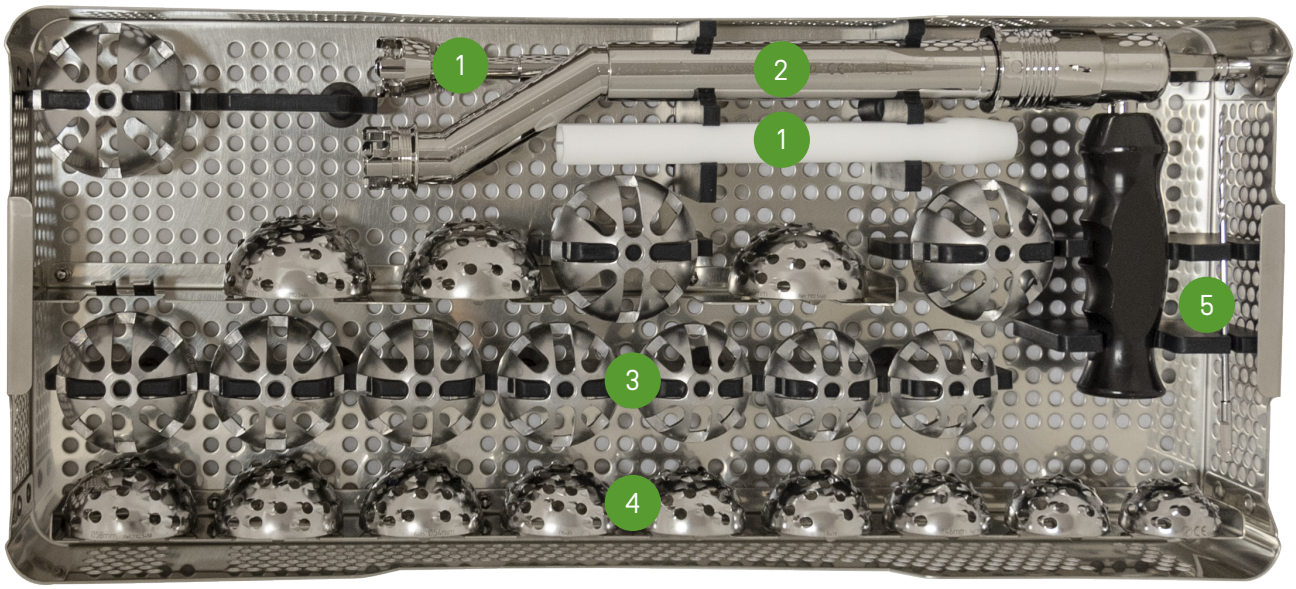


APPENDICES

APPENDIX 1
INSTRUMENT REFERENCES

Cup Instrumentation

REF 7231 1000



Level 1

	Description	Reference	Quantity
-	Case	7001 6010	1
1	Straight reamer-handle*	50244550*	1
2	Offset reamer-handle*	50244501*	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

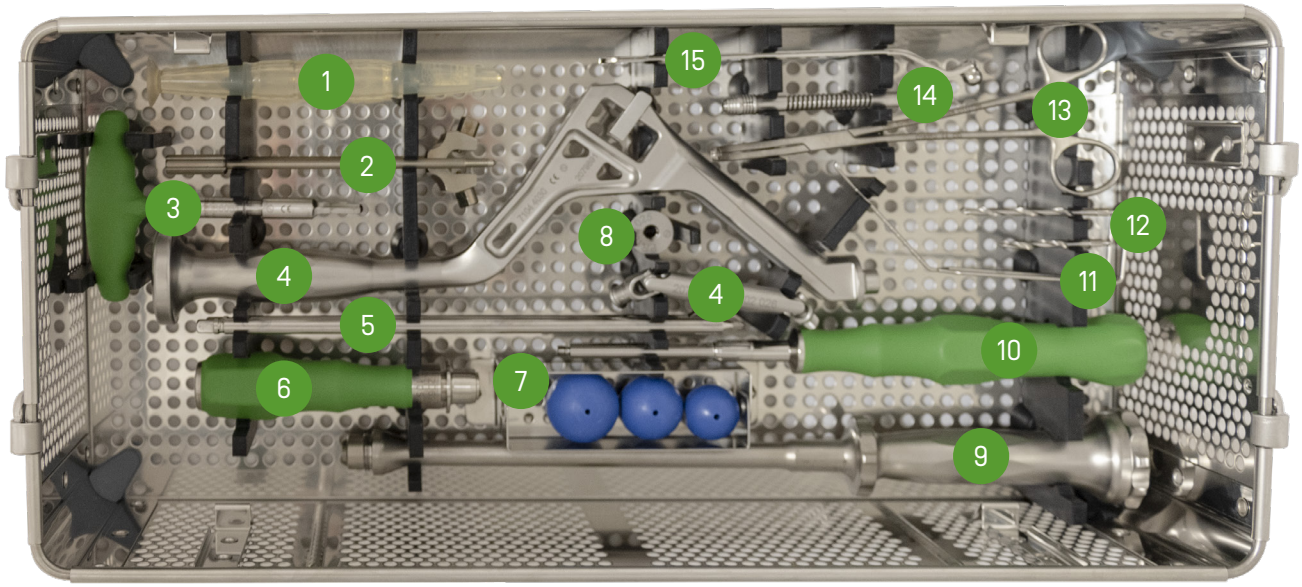
	Description	Reference	Quantity
4	Reamer Ø42*	T15473*	1
	Reamer Ø44*	T15475*	1
	Reamer Ø46*	T15477*	1
	Reamer Ø48*	T15479*	1
	Reamer Ø50*	T15481*	1
	Reamer Ø52*	T15483*	1
	Reamer Ø54*	T15485*	1
	Reamer Ø56*	T15487*	1
	Reamer Ø58*	T15489*	1
	Reamer Ø60*	T15491*	1
	Reamer Ø62*	T15493*	1
	Reamer Ø64*	T15495*	1
5	AO Drill bit Ø3.2 mm x 145 mm*	T878*	2

*CE mark held by another manufacturer

APPENDIX 1
INSTRUMENT REFERENCES

Cup Instrumentation

REF 7231 1000



Level 2

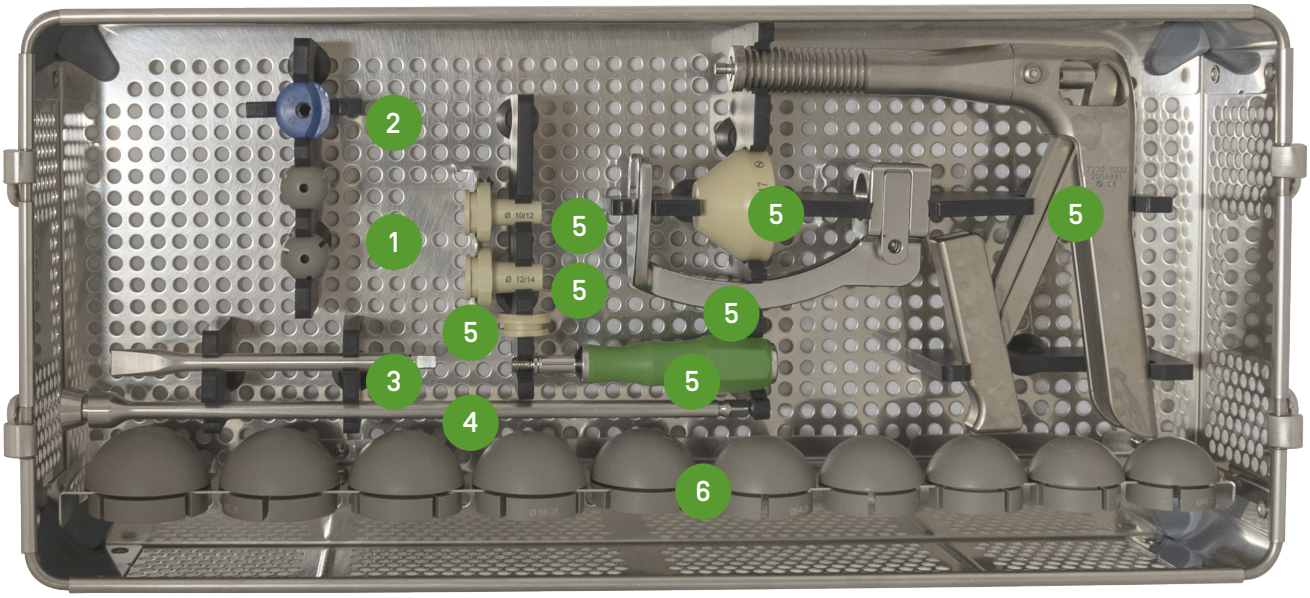
	Description	Reference	Quantity
-	Case	7001 6009	1
	Lid	7001 2011	1
1	Suction cup for ceramic insert	7104 4002	1
2	Cup positioner	7105 2016	1
3	T handle	PR100 011	1
4	Offset cup impactor	7104 4030 or 7104 4020	1
	Offset cup impactor cardan	PR102 026 or PR100 008	1
5	Cardan-shaft hex screwdriver bit	7104 6002	1
	Straight hex screwdriver bit	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	SERENITY® Adapter	7230 3001	1
9	Straight cup impactor	7104 4012 or 7104 4010	1
10	Screwable impactor	7004 1000	1
11	Depth gauge	7105 3001	1
12	Drill bit Ø3.2 mm x 40 mm*	367-1449*	2
	Drill bit Ø3.2 mm x 60 mm*	367-1451*	2
13	Screw holder*	D11273M*	1
14	Flexible shaft*	367-1457*	2
15	Drill guide Ø3.2 mm	7105 1006	1

*CE mark held by another manufacturer

APPENDIX 1
INSTRUMENT REFERENCES

SERENITY® Add-On Instrumentation

REF 7232 0000



	Description	Reference	Quantity
-	Case	7001 6011	1
	Lid	7001 2011	1
1	Trial head Ø22.2 mm / -2 mm	7003 4122	1
	Trial head Ø22.2 mm / 0 mm	7003 4222	1
2	Repositioner end-cap	7105 2020	1
3	SERENITY® Flange bender	7230 1001	1
4	SERENITY® Gripper	7230 1002	1
5	SERENITY® Press	7230 1000	1
6	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

Optional

-	Unlock wrench	7104 7005	1
-	SERENITY® Adapter	7230 3000	1

APPENDIX 2
IMPLANT REFERENCES

SERENITY® Cemented
Dual-mobility cemented cup
Stainless steel (M30NW-ISO 5832-9)

Sizes	Ref.	Head compatibility	
		Ø 22.2	**Ø 28**
42*	1031 4200*	•	
44*	1031 4400*	•	
46	1031 4600	•	
48	1031 4800		•
50	1031 5000		•
52	1031 5200		•
54	1031 5400		•
56	1031 5600		•
58	1031 5800		•
60	1031 6000		•
62*	1031 6200*		•

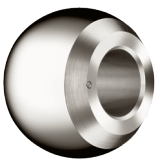
SERENITY® Insert
Dual-mobility insert. Polyethylene (UHMWPE-ISO 5834-1).

Cup sizes	**Ø 22.2**	**Ø 28**
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

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

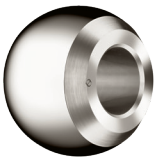
Sizes	Offset in mm		
	-3.5	**+0**	**+3.5**
ø 28	2014 2801	2014 2802	2014 2803**

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**
ø 22.2	-	2010 2201	2010 2202	-
ø 28	2010 2801	-	2010 2802	2010 2803**

Stainless Steel Head
Stainless steel head (M30NW-ISO 5832-9), compatible with 12/14 5°40' taper.



Sizes	Offset in mm		
	-3.5	**+0**	**+3.5**
ø 28	2011 2801	2011 2802	2011 2803**

* Only available upon request

**Not recommended for use with Symbios® INDIVIDUAL HIP® and SPS® HA stems.

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