HARMONY[®] Evolution Hip System

Surgical technique HARMONY® Evolution Hip System







INTRODUCTION

The HARMONY® Evolution Hip System

Concept

The HARMONY[®] Evolution system was designed to capitalize on both the clinically proven concept of straight stems^[1] and Symbios' 30 years of experience in 3D planning for personalised and standard prostheses. In line with this objective, the HARMONY[®] Evolution system offers a complete range of extramedullary solutions with straight and lateralised stems both available in cementless and cemented variants, supported by 3D planning using HIP-PLAN[®] software provided to surgeons.

The stems are indicated for primary total hip replacements.

The instrumentation of the HARMONY® Evolution stems is suitable for all surgical approaches.





Flexibility in choice of fixation



- Self-locking quadrangular design
- Horizontal grooves for primary stability



Easier osteointegration

Hydroxyapatite coating on the entire stem Thickness 120 +/- 35 μm



To guarantee metaphyseal anchoring



Slotted recess for control in rotation

Impaction hole with slotted recess to control rotation during stem impaction and to support during cementation



- CCD angle of 129° for the HARMONY[®] Standard stems
- CCD angle of 125° for the HARMONY® Offset stems
- 12/14 5°40' standard cone

Smooth polishing Smooth surface for optimal cement implant interface performance

Osteotomy level

Easier identification of blocking angle of fixation

«French Paradox» cement

The design allows the prosthesis to be placed neutral in the femur, regardless of morphology. The bone prosthesis interface is fixed by a thin cement mantle, thus minimizing risks of detachment and also protecting the bone from resorption.^[2]



Femur

Switch from cementless to cemented peroperatively

The instrument platform HARMONY[®] is common to both cementless and cemented system fixation and is therefore interchangeable peroperatively.



PREOPERATIVE PROCESS IN HIP-PLAN®

Analysis of the native anatomy



3D-planning of the stem



• Precisely determine in 3 dimensions the positioning of the stem, as well as its size and anteversion.

Load the patient CT-scan in the HIP-PLAN®

Determine the femoral head and acetabular

Determine the native acetabular anteversion

software.

diameter of the patient.

and inclination.

• Examine the functional behaviour of implants thanks to the combination of multi-plan views with the surface view of the pelvis, in order to avoid oversizing which can lead to conflict with the iliopsoas muscle during the postoperative period.

Evaluation of the final reconstruction



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

SURGICAL TECHNIQUE

SURGICAL STEPS

In this surgical technique, some steps and instruments are common with surgical techniques of other Symbios femoral stems.

Surgical technique

| 1. 2. 3. 4. 5. | Material preparation Exposure Preparation of the femur Functional trials Implantation • HARMONY® Evolution Stems • HARMONY® Evolution Cemented Stems Final reduction | STEP 1 STEP 2 STEP 3 STEP 4 STEP 5 STEP 6 | P. 8 P. 9 P. 10-11 P. 12 P. 13-14 P. 13 P. 14 P. 15 |
|----------------------------|---|--|--|
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STEP 1 MATERIAL PREPARATION

Instrumentation

7002 0000 Standard Stems Instrumentation

This instrumentation is required to perform the steps from the femoral preparation to the impaction for all Symbios stems including HARMONY[®] Evolution.

With this set, all surgical approaches are managed.



Level 1



Level 2

7093 0000 HARMONY® Rasps Instrumentation

This instrumentation contains all the trial components [trial necks and rasps] for all stems from the ${\rm HARMONY}^{\circledast}$ Evolution system.



TO ORDER ACCORDING TO THE SURGICAL APPROACH

7006 1020 Double offset rasp handle - Right 7006 1021 Double offset rasp handle - Left



7006 1024 Hueter rasp handle



7006 1022 Single offset rasp handle - Right 7006 1023 Single offset rasp handle - Left



STEP 2 EXPOSURE

2.1 Surgical approach

• Determine the surgical approach based on surgery preferences and indications. (Fig.1)







2.2 Opening of the joint capsule

femoral neck. (Fig.2)

Perform the osteotomy of the femoral head with an oscillating saw in accordance with preoperative planning.
[Fig.3]

After opening the joint capsule, remove tissue at the

- Extract the femoral head.
- > **HIP-PLAN® tip :** The height of the resection can be measured and compared to that in the planning report.

At the end of this step, proceed to the preparation of the acetabulum by referring both to the specific surgical technique of the planned cup (and the HIP-PLAN[®] preoperative report planning when available).



STEP 3 PREPARATION OF THE FEMUR







3.1 Preparation of the entry of the femoral canal

- Once the acetabular preparation is done and the cup implanted, expose the femur.
- Take care to expose the whole femoral canal by means of retractors placed according to the surgical approach.
- Remove all fibrous and cartilage tissues or osteophytes that may interfere with the preparation of the femur with a curette or a long gouge.
- With the help of the modular box chisel previously assembled with the rasp handle which is the same rectangular shape as the HARMONY® Evolution stem, prepare the entry of the femoral canal. [Fig.4]

3.2 Preparation of the femoral canal

- With the help of the small reamer previously assembled with the T-handle, prepare the canal. [Fig.5]
- A starter rasp can be used to prepare the femur before the insertion of the first HARMONY® rasp. [Fig.6]



Instruments 🔨













Long gouge 7002 1002

Modular box chisel 7004 4017

Straight rasp handle **7006 1019**

Curved starter rasp 7012 2005

Small reamer **7002 3002**

amer **)2**

T-handle 7019 4001

STEP 3 PREPARATION OF THE FEMUR

3.3 Impaction of the rasp

- Insert the rasp with the appropriated rasp handle according to the surgical approach. (Fig.7)
- The rasp should run parallel to the inner cortex of the femur, following the natural anatomy of the femur. [Fig.8]
- Gradually increase the size of the HARMONY® rasp (size by size), taking into account the final position and anteversion of the stem. Impact the rasp with a hammer.
- Check the stability of the rasp until a good longitudinal and rotational stability is achieved. [Fig.9]
- > **HIP-PLAN® tip:** The size of the rasp can begin two sizes below the planned size defined in the planning report.







Instruments 🔨



Straight rasp handle 7006 1019



HARMONY® rasp 709142xx

STEP 4 FUNCTIONAL TRIALS





4.1 Insertion of the trial neck

- Select the trial neck according to the stem and size to be implanted based on the specificity described below.
 - HARMONY[®] Evolution Standard - Purple trial necks:
 - Pink trial necks: HARMONY® Evolution Offset
- Note the orientation of the trial neck. [Fig.10]





Insert the trial neck in the HARMONY® rasp.

- The insert has been impacted in the cup.
- Thanks to the head impaction end-cap assembled with the screwable impactor, perform the reduction of the trial head in the insert.
- Perform functional tests to control the mobility and stability of the joint, if necessary by changing the offset of the trial head. (Fig.11)

4.2 Extraction of the trial implants

- Dislocate the hip joint to disassemble the trial head [assembled with the trial neck] and the insert. [Fig.12]
- Remove all the trial implants and the rasp.
- Clean the femoral canal.

Instruments A





Offset trial neck

or





HARMONY[®] Evolution Standard trial neck 7073 90xx

HARMONY® Evolution 7073 90xx

Trial head 7003 4xxx

Head impaction end-cap 7004 3656



Screwable impactor 7004 1000

STEP 5 IMPLANTATION

CEMENTLESS STEMS

5.1 Impaction of the stem

- Select the HARMONY[®] Evolution stem of the same size as the final rasp.
- > **Important:** The taper protective cover should be left on until the components are ready to be implanted.
- Insert by hand the stem to ensure that it is directed in the femoral canal.
- Tap the stem with the half-moon stem impactor to fully seat the stem. [Fig.13, 14]
- Information: The final position is checked by alignment of the upper edge of the hydroxyapatite coating, which must be located at the level of the osteotomy line and parallel to it. If the stem does not readily go down this far, the rasp should be used again. If the hydroxyapatite coating level of the stem is below the resection line, a larger stem should be considered.



Caution: HA-coated implants must not be implanted with cement.





Instruments ^



Half-moon stem impactor **7004 4008**

STEP 5 IMPLANTATION









CEMENTED STEMS

5.2 Cement restrictor trial

- Select the size of the trial cement restrictor identified to fit the distal canal.
- Attach it to the cement restrictor handle and insert the trial cement restrictor to the planned depth. (Fig.15)
- Check that it is firmly seated in the canal. Remove the trial cement restrictor.

5.3 Cement restrictor insertion

- Insert the selected cement restrictor implant at the same level as the restrictor trial, see manufacturer instructions. [Fig.16]
- > **Important:** The size of the cement restrictor should be the same size than the last trial restrictor inserted to the planned level. The planned level should be 1 cm below the tip of the implant.

5.4 Cementation of the stem

- Prepare the cement according to the manufacturer instructions.
- Inject the cement into the bone cavity. [Fig.17]
- Select the HARMONY[®] Evolution Cemented stem of the same size as the final rasp.
- > **Important:** The taper protective cover should be left on until the components are ready to be implanted.
- Insert the stem and maintain it strongly until the cement hardens with the help of the half-moon stem impactor positionned in the slot of the stem.
- Remove the cement surplus before the cement is dry.

Instruments 🔨



Half-moon stem impactor **7004 4008**

STEP 6 FINAL REDUCTION

6.1 Impaction of the head

- Clean and dry the neck of the stem of any blood, bone chips or other foreign materials.
- According to the reduction trials, select the appropriate head and place it onto the neck.
- Impact the head on the stem by using the head impaction end-cap assembled with the screwable impactor. (Fig.18)







• Perform the final reduction of the implant with the head

6.2 Final reduction

- impaction end-cap assembled with the screwable impactor. [Fig.19]
- Carry out mobility and joint stability tests with all final implants.

6.3 Closure

• Close the joint and the wound in a standard manner. [Fig.20]





Head impaction end-cap 7004 3656

Screwable impactor



APPENDICES





APPENDIX 1 PEROPERATIVE EXTRACTION

HARMONY[®] Evolution extraction

- Use the reversible extractor with the M8 x 1 tip to extract the stem with a hammer during the initial surgery. [Fig.21]
- Connect the extractor in the slot of the stem, then extract the stem by hammering on the impaction plate of the extractor. [Fig.22]
- > **Caution:** If the taper of the stem is damaged, do not re-insert the stem. Implant a new femoral stem.





Instruments 🔨

Reversible extractor M8 7004 4018

APPENDIX 2 IMPLANT REFERENCES



HARMONY® Evolution Standard

Cementless straight femoral stem. Titanium alloy (Ti6Al4V-ISO 5832-3). Coating: Hydroxyapatite. 12/14 5°40' taper. CCD shaft angle 129°.

| Sizes | Ref. | Length |
|-------|------------|--------|
| 8* | 3031 0801* | 115 mm |
| 9 | 3031 0901 | 130 mm |
| 10 | 3031 1001 | 140 mm |
| 11 | 3031 1101 | 145 mm |
| 12 | 3031 1201 | 150 mm |
| 13 | 3031 1301 | 155 mm |
| 14 | 3031 1401 | 160 mm |
| 15 | 3031 1501 | 165 mm |
| 16 | 3031 1601 | 170 mm |
| 18 | 3031 1801 | 180 mm |
| 20 | 3031 2001 | 190 mm |



*Maximum weight limit 70 kg

HARMONY® Evolution Standard Cemented

Cemented straight femoral stem. Stainless steel (M30NW-ISO 5832-9), smooth polished. 12/14 5°40' taper. CCD shaft angle 129°.

| Sizes | Ref. | Length |
|-------|-----------|--------|
| 8 | 3034 0801 | 115 mm |
| 9 | 3034 0901 | 130 mm |
| 10 | 3034 1001 | 140 mm |
| 11 | 3034 1101 | 145 mm |
| 12 | 3034 1201 | 150 mm |
| 13 | 3034 1301 | 155 mm |
| 14 | 3034 1401 | 160 mm |
| 15 | 3034 1501 | 165 mm |
| 16 | 3034 1601 | 170 mm |



APPENDIX 2 IMPLANT REFERENCES

HARMONY® Evolution Offset

Cementless straight femoral stem with offset and varus. Titanium alloy (Ti6Al4V-ISO 5832-3). Coating: Hydroxyapatite. 12/14 5° 40' taper. CCD shaft angle 125°.

| Sizes | Ref. | Length |
|-------|-----------|--------|
| 9 | 3032 0900 | 130 mm |
| 10 | 3032 1000 | 140 mm |
| 11 | 3032 1100 | 145 mm |
| 12 | 3032 1200 | 150 mm |
| 13 | 3032 1300 | 155 mm |
| 14 | 3032 1400 | 160 mm |
| 15 | 3032 1500 | 165 mm |
| 16 | 3032 1600 | 170 mm |
| 18 | 3032 1800 | 180 mm |



HARMONY® Evolution Offset Cemented

Cemented straight femoral stem with offset and varus. Stainless steel (M30NW-ISO 5832-9), smooth polished. 12/14 5° 40' taper. CCD shaft angle 125°.

| Sizes | Ref. | Length |
|-------|-----------|--------|
| 8 | 3035 0800 | 115 mm |
| 9 | 3035 0900 | 130 mm |
| 10 | 3035 1000 | 140 mm |
| 11 | 3035 1100 | 145 mm |
| 12 | 3035 1200 | 150 mm |
| 13 | 3035 1300 | 155 mm |
| 14 | 3035 1400 | 160 mm |
| 15 | 3035 1500 | 165 mm |
| 16 | 3035 1600 | 170 mm |



APPENDIX 2 IMPLANT REFERENCES

22

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

| Sizes | | | Offset in mm | | | | |
|-------|-----------|-----------|--------------|-----------|-----------|-----------|-----------|
| | -4 | -3.5 | +0 | +3.5 | +4 | +7 | +8 |
| ø28 | - | 2014 2801 | 2014 2802 | 2014 2803 | - | - | - |
| ø32 | 2014 3201 | _ | 2014 3202 | - | 2014 3203 | 2014 3204 | - |
| ø36 | 2014 3601 | - | 2014 3602 | - | 2014 3603 | - | 2014 3604 |



Cobalt-chrome head (CoCrMo-ISO 5832-12), compatible with 12/14 5°40' taper.

| Sizes | Offset in mm | | | | | | | |
|-------|--------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| | -4 | -3.5 | -2 | +0 | +3.5 | +4 | +7 | +8 |
| ø22.2 | - | _ | 2010 2201 | 2010 2202 | - | 2010 2204 | - | - |
| ø28 | - | 2010 2801 | - | 2010 2802 | 2010 2803 | - | 2010 2804 | - |
| ø32 | 2010 3201 | _ | - | 2010 3202 | - | 2010 3203 | - | 2010 3204 |
| ø36 | 2010 3601 | - | - | 2010 3602 | - | 2010 3603 | - | 2010 3604 |

Stainless Steel Head

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

| Sizes | | | Offset in mm | | | | |
|-------|-----------|-----------|--------------|-----------|-----------|-----------|-----------|
| | -4 | -3.5 | +0 | +3.5 | +4 | +7 | +8 |
| ø28 | _ | 2011 2801 | 2011 2802 | 2011 2803 | - | 2011 2804 | - |
| ø32 | 2011 3201 | - | 2011 3202 | - | 2011 3203 | - | 2011 3204 |









Standard Stems Instrumentation

REF 7002 0000

Symbios



Level 1

| | Description | Reference | Quantity |
|---|-------------------------|--------------------|----------|
| 1 | Long gouge | 7002 1002 / PN2607 | 1 |
| 2 | Small reamer | 7002 3002 | 1 |
| 3 | Modular box chisel | 7004 4017 | 1 |
| 4 | T-handle | 7019 4001/T15757 | 1 |
| 5 | Screwable impactor | 7004 1000 | 1 |
| 6 | Monobloc stem impactor | 7004 4001 | 1 |
| 7 | Half-moon stem impactor | 7004 4008 | 1 |
| 8 | Hex screwdriver 3.5 | 7018 1005/T15320 | 1 |
| 9 | Head impaction end-cap | 7004 3656 | 1 |

APPENDIX 3 INSTRUMENT REFERENCES

Standard Stems Instrumentation

REF 7002 0000



Level 2

| | Description | Reference | Quantity |
|---|---------------------------|-----------|----------|
| 1 | Curved starter rasp | 7012 2005 | 1 |
| 2 | Straight rasp handle | 7006 1019 | 1 |
| 3 | Reversible extractor M8 | 7004 4018 | 1 |
| | Trial head Ø28 mm/-3.5 mm | 7003 4128 | 1 |
| 4 | Trial head Ø28 mm/+0 mm | 7003 4228 | 1 |
| 4 | Trial head Ø28 mm/+3.5 mm | 7003 4328 | 1 |
| | Trial head Ø28 mm/+7 mm | 7003 4428 | 1 |
| | Trial head Ø32 mm/-4 mm | 7003 4132 | 1 |
| F | Trial head Ø32 mm/+0 mm | 7003 4232 | 1 |
| 5 | Trial head Ø32 mm/+4 mm | 7003 4332 | 1 |
| | Trial head Ø32 mm/+8 mm | 7003 4432 | 1 |
| | Trial head Ø36 mm/-4 mm | 7003 4136 | 1 |
| 0 | Trial head Ø36 mm/+0 mm | 7003 4236 | 1 |
| 0 | Trial head Ø36 mm/+4 mm | 7003 4336 | 1 |
| | Trial head Ø36 mm/+8 mm | 7003 4436 | 1 |
| | | | |

Optional

| - | Double offset rasp handle - Right | 7006 1020 | 1 |
|---|-----------------------------------|-----------|---|
| - | Double offset rasp handle - Left | 7006 1021 | 1 |
| - | Single offset rasp handle - Right | 7006 1022 | 1 |
| - | Single offset rasp handle - Left | 7006 1023 | 1 |
| - | Hueter rasp handle | 7006 1024 | 1 |



APPENDIX 3 INSTRUMENT REFERENCES

HARMONY® Rasps Instrumentation

REF 7093 0000



| | Description | Reference | Quantity |
|---|--|-----------|----------|
| 1 | HARMONY [®] Evolution Standard trial neck 8-9 | 7073 9013 | 1 |
| | HARMONY [®] Evolution Standard trial neck 10 | 7073 9014 | 1 |
| | HARMONY [®] Evolution Standard trial neck 11 | 7073 9015 | 1 |
| | HARMONY® Evolution Standard trial neck 12 | 7073 9016 | 1 |
| | HARMONY® Evolution Standard trial neck 13-20 | 7073 9017 | 1 |
| 2 | HARMONY [®] Evolution Offset trial neck 8 | 7073 9018 | 1 |
| | HARMONY [®] Evolution Offset trial neck 9 | 7073 9019 | 1 |
| | HARMONY [®] Evolution Offset trial neck 10 | 7073 9020 | 1 |
| | HARMONY [®] Evolution Offset trial neck 11 | 7073 9021 | 1 |
| | HARMONY [®] Evolution Offset trial neck 12 | 7073 9022 | 1 |
| | HARMONY [®] Evolution Offset trial neck 13 | 7073 9023 | 1 |
| | HARMONY [®] Evolution Offset trial neck 14 | 7073 9024 | 1 |
| | HARMONY [®] Evolution Offset trial neck 15 | 7073 9025 | 1 |
| | HARMONY [®] Evolution Offset trial neck 16 | 7073 9026 | 1 |
| | HARMONY [®] Evolution Offset trial neck 18 | 7073 9027 | 1 |
| 3 | HARMONY [®] rasp 8 | 7091 4208 | 1 |
| | HARMONY [®] rasp 9 | 7091 4209 | 1 |
| | HARMONY [®] rasp 10 | 7091 4210 | 1 |
| | HARMONY [®] rasp 11 | 7091 4211 | 1 |
| | HARMONY [®] rasp 12 | 7091 4212 | 1 |
| | HARMONY [®] rasp 13 | 7091 4213 | 1 |
| | HARMONY [®] rasp 14 | 7091 4214 | 1 |
| | HARMONY [®] rasp 15 | 7091 4215 | 1 |
| | HARMONY [®] rasp 16 | 7091 4216 | 1 |
| | HARMONY® rasp 18 | 7091 4218 | 1 |
| | HARMONY [®] rasp 20 | 7091 4220 | 1 |

References

[1] Medium- and long-term performance of 11,516 uncemented primary femoral stems from the Norwegian arthroplasty register Hallan G, Lie SA, Furnes O, Engesaeter LB, Vollset SE, Havelin LI

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Skinner JA, Todo S, Taylor M, Wang JS, Pinskerova V, Scott G Journal of Bone and Joint Surgery (British) 2003, vol. 85, n°1

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