NOVAE®

DUAL MOBILITY CUPS

SURGICAL TECHNIQUE

serf
HIP

CONTENT

PRESENTATION OF THE DUAL MOBILITY

The **NOVAE**® range of acetabular cups is intended for primary total hip arthroplasty and revision cases, with and without cement. **NOVAE**® acetabular cups are based on the dual mobility concept invented in 1974 by Prof. Gilles BOUSQUET of the Saint Etienne University Hospital and Mr André RAMBERT, founder of SERF.

The consideration of 2 fundamental orthopaedic principles led to developing this concept:

- Sir Charnley's low friction principle which recommends using a significant thickness of polyethylene and a femoral head ø 22.2 mm to reduce wear of the friction torque
- McKee-Farrar's principle which recommends using a femoral head with a large diameter to reduce the risk of dislocation and prosthetic instability.

The dual mobility therefore consists of a first mobility which is the mobility of the head in the liner (small articulation), and a second mobility (large articulation) which corresponds to the mobility of the liner in the cup as shown below:

THE SMALL ARTICULATION (OR 1ST MOBILITY)
Head Ø 22,2 mm / α = 51°
Head Ø 28 mm / α = 76°

THE LARGE ARTICULATION (OR 2ND MOBILITY)
Ø 43 mm / β = 126°
Ø 65 mm / β = 140°

This characteristic allows to significantly increase the «jump distance» (distance between the top of the femoral head and the outermost point of the cup) and thereby reduce the risk of dislocation, whether by decoaptation of the articular surfaces or by impingement, through contact between the neck of the prosthesis and the edge of the metal cup.

A total hip replacement with a **NOVAE®** dual mobility cup is made up of the following:

1. The cup made of forged stainless steel
2. The mobile liner in polyethylene
3. The metal or ceramic femoral head
4. The femoral stem that must have a neck that is preferably smooth and polished to a shine without any sharp corners because of the normal but repetitive contact between the polyethylene liner and the prosthetic neck.

The different implants that make up the NOVAE® range are:

DESIGNATION	IMPLANT TYPE	MATERIALS
NOVAE® SUNFIT TH	Cementless cup for primary THA	X18M25W (ISO5832-1) stainless steel and titanium spray + HA coating
NOVAE® E TH	Cementless cup for primary and/or small revision THA with tripod attachment system obtained using 2 pegs and a flange in which a fixation screw is used	X18M25W (ISO5832-1) stainless steel and spray + HA coating Pegs: Stainless steel with alumina coating
NOVAE® COPTOS TH	Cementless cup for revision THA with 2 pegs and two flanges in which 4 fixation screws can be used	X18M25W (ISO5832-1) stainless steel and titanium spray + HA coating Pegs: Stainless steel with alumina coating
NOVAE® STICK	Cemented cup	Stainless steel X18M25W (ISO5832-1)
NOVAE® K E	Cross-plate reinforcement ring intended to be used with NOVAE® STICK cup	Stainless steel X18M25W (ISO5832-1)
Insert CI E	Dual mobility liner (common to all NOVAE® cups)	Polyethylene X18M25W (ISO5832-1)
VCI Screw	Cortical screw Ø 5 mm	Stainless steel X18M25W (ISO 5832-1)

NOVAE® ACETABULAR CUP CHARACTERISTICS

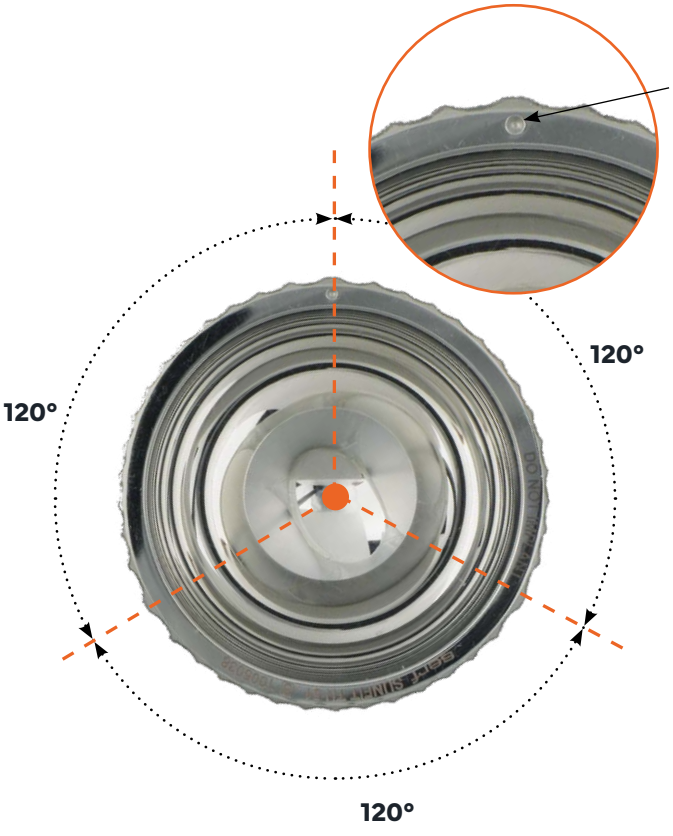
All of the **NOVAE®** acetabular cups are hemispherical with a 3 mm cylinder added to form a cylinder-spherical type shape.

They gradually flatten from the top following a wide radius (0.5 mm maximum), which contributes to absorbing the stress at the bottom of the cup on final impaction.

The internal surface of the cups is completely polished to allow articulation of the dual mobility.

The cementless cups have an equatorial press-fit to encourage primary fixation of the implant to the bone. The secondary fixation is provided by the dual coating of titanium spray (thickness 150±30 µm) and HA coating (thickness 70±20 µm), on the outer surface of the cementless cups.

All of the **NOVAE®** acetabular cementless cups come with their pre-assembled polyethylene cup gripper (single use) and the **NOVAE® STICK** cup comes with a disposable cup impactor (also single use).



NOVAE® SUNFIT TH

The **NOVAE® SUNFIT TH** cup is an acetabular cementless implant intended for primary total hip replacement (THR).

To ensure primary fixation, the cup has 3 points (a few tenths of millimetres higher) that divide the acetabular cup into three 120° segments.
The equatorial press-fit is distributed around these 3 points. The press-fit's height and thickness change according to the cup's diameter (minimum 1.2 mm, maximum 2.1 mm).

A mechanical marker is placed on the implant edge so that the point to be attached to the ilium can be located.

NOVAE® E TH

The **NOVAE® E TH** cup is an acetabular cementless implant intended for primary total hip replacement (THR) and small revision.

To ensure primary fixation, the **NOVAE® E TH** cup has both a press-fit and a tripod attachment system: 1 peg in the ischium, 1 peg in the pubis, and 1 cortical screw in the ilium through the malleable flange. This concept of 3 anchoring points was devised by Prof. Gilles BOUSQUET to ensure primary stability during rotation and pull-out of the **NOVAE® E TH** acetabular cup.

NOVAE® COPTOS TH

The **NOVAE® COPTOS TH** cup is an acetabular implant intended for cementless acetabular reconstruction. Primary fixation of the **NOVAE® COPTOS TH** is obtained by equatorial press-fit complemented by 2 pegs, 2 flanges (which can place up to 4 fixation screws in the ilium), and 1 hook. The hook, previously placed in the obturator hole, allows for anatomical repositioning and provides additional mechanical support.

The 2 flanges are malleable and scored to adapt to different cases of acetabular reconstructions.

NOVAE® STICK

The **NOVAE® STICK** cup is an acetabular implant intended to be attached to the bone with surgical cement.

The external surface has raised reliefs that allow for the evacuation of excess cement and promote stability when it is polymerised. The **NOVAE® STICK** cup can be cemented directly through contact with the bone or in a fitting at the bottom of the acetabulum: the **NOVAE® K E** cross-plate.

NOVAE® KE CROSS-PLATE

The **NOVAE® K E** cross-plate is intended to recreate a background necessary for the implantation of a **NOVAE® STICK** cup for cemented acetabular revision cases.

The **NOVAE® K E** cross-plate is anatomical and is available for right and left side acetabular revision cases.

The **NOVAE® K E** cross-plate features:

- 2 flanges, one of which is shorter to adapt to the side being operated on
- 1 obturator hook intended to rest under the lower fringe of the cup and allow the anatomical repositioning of the hip
- 1 impaction plate with 4 holes for the 5 mm diameter screws
- 4 PMMA (polymethylmethacrylate) spacing pegs located in the 4 "arms" of the cross. They make it possible to center the cemented acetabular implant and to properly distribute the cement. In addition, the pegs prevent direct contact between the cemented acetabular cup and the cross-plate.

NOVAE® RANGE

NOVAE® SUNFIT TH
Ø 43 TO 69 MM

NOVAE® E TH
Ø 41 TO 69 MM

The CI/E liners are compatible with all of the **NOVAE®** cups, respecting the size they will be used with.
In primary total hip replacement, using Ø 22.2 diameter heads up to size 51 inclusive allows a considerable thickness of UHMWPE.

NOVAE® COPTOS TH
Ø 43 TO 69 MM

NOVAE® STICK
Ø 43 TO 63 MM

NOVAE® K E
TAILLE 50/43 TO 60/53 MM
RIGHT & LEFT SIDES

VCI CORTICAL SCREWS
Ø 5 MM LG 20 TO 70MM

CI/E LINERS
THICKNESS IN MM

SIZE	HEAD 22,2MM	HEAD 28MM
Ø 41	6,1	/
Ø 43	6,9	/
Ø 45	7,9	/
Ø 47	8,9	6,1
Ø 49	9,9	7
Ø 51	10,9	8
Ø 53	11,9	9
Ø 55	12,8	9,9
Ø 57	13,8	10,9
Ø 59	14,8	11,9
Ø 61	15,8	12,9
Ø 63	16,8	13,9
Ø 65	17,8	14,9
Ø 67	18,8	15,9
Ø 69	19,8	16,9

IMPLANTS REFERENCES

NOVAE® SUNFIT TH

REFERENCES	DESIGNATION	SIZE
RM45320002	SUNFIT TH 43	Ø 43*
RM45320003	SUNFIT TH 45	Ø 45
RM45320004	SUNFIT TH 47	Ø 47
RM45320005	SUNFIT TH 49	Ø 49
RM45320006	SUNFIT TH 51	Ø 51
RM45320007	SUNFIT TH 53	Ø 53
RM45320008	SUNFIT TH 55	Ø 55
RM45320009	SUNFIT TH 57	Ø 57
RM45320010	SUNFIT TH 59	Ø 59
RM45320011	SUNFIT TH 61	Ø 61
RM45320012	SUNFIT TH 63	Ø 63*
RM45320013	SUNFIT TH 65	Ø 65*
RM45320014	SUNFIT TH 67	Ø 67*
RM45320015	SUNFIT TH 69	Ø 69*

*Optional sizes available on request with a specific instrumentation set

NOVAE® E TH

REFERENCES	DESIGNATION	SIZE
RM45050001	NOVAE® E 41 TH	Ø 41*
RM45050002	NOVAE® E 43 TH	Ø 43
RM45050003	NOVAE® E 45 TH	Ø 45
RM45050004	NOVAE® E 47 TH	Ø 47
RM45050005	NOVAE® E 49 TH	Ø 49
RM45050006	NOVAE® E 51 TH	Ø 51
RM45050007	NOVAE® E 53 TH	Ø 53
RM45050008	NOVAE® E 55 TH	Ø 55
RM45050009	NOVAE® E 57 TH	Ø 57
RM45050010	NOVAE® E 59 TH	Ø 59
RM45050011	NOVAE® E 61 TH	Ø 61
RM45050012	NOVAE® E 63 TH	Ø 63*
RM45050013	NOVAE® E 65 TH	Ø 65*
RM45050014	NOVAE® E 67 TH	Ø 67*
RM45050015	NOVAE® E 69 TH	Ø 69*

NOVAE® COPTOS TH

REFERENCES	DESIGNATION	SIZE
RM45360001	COPTOS 43 TH	Ø 43*
RM45360002	COPTOS 45 TH	Ø 45
RM45360003	COPTOS 47 TH	Ø 47
RM45360004	COPTOS 49 TH	Ø 49
RM45360005	COPTOS 51 TH	Ø 51
RM45360006	COPTOS 53 TH	Ø 53
RM45360007	COPTOS 55 TH	Ø 55
RM45360008	COPTOS 57 TH	Ø 57
RM45360009	COPTOS 59 TH	Ø 59
RM45360010	COPTOS 61 TH	Ø 61
RM45360011	COPTOS 63 TH	Ø 63*
RM45360012	COPTOS 65 TH	Ø 65*
RM45360013	COPTOS 67 TH	Ø 67*
RM45360014	COPTOS 69 TH	Ø 69*

NOVAE® STICK

REFERENCES	DESIGNATION	SIZE
RM49010000	NOVAE® STICK 43	Ø 43*
RM49010001	NOVAE® STICK 45	Ø 45
RM49010002	NOVAE® STICK 47	Ø 47
RM49010003	NOVAE® STICK 49	Ø 49
RM49010004	NOVAE® STICK 51	Ø 51
RM49010005	NOVAE® STICK 53	Ø 53
RM49010006	NOVAE® STICK 55	Ø 55
RM49010007	NOVAE® STICK 57	Ø 57
RM49010008	NOVAE® STICK 59	Ø 59
RM49010009	NOVAE® STICK 61	Ø 61
RM49010010	NOVAE® STICK 63	Ø 63*

NOVAE® K E

	REFERENCES	DESIGNATION
LEFT SIDE	RM48010150	K E 50/43 G
	RM48010152	K E 52/45 G
	RM48010154	K E 54/47 G
	RM48010156	K E 56/49 G
	RM48010158	K E 58/51 G
	RM48010160	K E 60/53 G
RIGHT SIDE	RM48010050	K E 50/43 D
	RM48010052	K E 52/45 D
	RM48010054	K E 54/47 D
	RM48010056	K E 56/49 D
	RM48010058	K E 58/51 D
	RM48010060	K E 60/53 D

VCI CORTICAL SCREW Ø 5 MM

REFERENCES	DESIGNATION
RM65150013	VCI 5 X 20
RM65150015	VCI 5 X 25
RM65150017	VCI 5 X 30
RM65150019	VCI 5 X 35
RM65150021	VCI 5 X 40
RM65150046	VCI 5 X 45
RM65150031	VCI 5 X 50
RM65150047	VCI 5 X 55
RM65150041	VCI 5 X 60
RM65150048	VCI 5 X 65
RM65150049	VCI 5 X 70

CI/E LINER

REFERENCES	22.2 LINER	REFERENCES	28 LINER
RM51100001	CI 41/22,2 E*	/	/
RM51100002	CI 43/22,2 E*	/	/
RM51100003	CI 45/22,2 E	/	/
RM51100004	CI 47/22,2 E	RM51100032	CI 47/28 E
RM51100005	CI 49/22,2 E	RM51100033	CI 49/28 E
RM51100006	CI 51/22,2 E	RM51100034	CI 51/28 E
RM51100007	CI 53/22,2 E	RM51100035	CI 53/28 E
RM51100008	CI 55/22,2 E	RM51100036	CI 55/28 E
RM51100009	CI 57/22,2 E	RM51100037	CI 57/28 E
RM51100010	CI 59/22,2 E	RM51100038	CI 59/28 E
RM51100012	CI 61/22,2 E	RM51100040	CI 61/28 E
RM51100013	CI 63/22,2 E*	RM51100041	CI 63/28 E*
RM51100014	CI 65/22,2 E*	RM51100042	CI 65/28 E*
RM51100015	CI 67/22,2 E*	RM51100043	CI 67/28 E*
RM51100016	CI 69/22,2 E*	RM51100044	CI 69/28 E*

*Optional sizes available on request with a specific instrumentation set

SURGICAL TECHNIQUE

1 PREOPERATIVE PLANNING

To ensure that the implants are correctly positioned, an X ray evaluation using the implants' templates supplied (or using the available planning software) is recommended.

This planning must be used to select the adequate acetabular cup to implant in terms of size and orientation.

2 ACETABULAR PREPARATION

The acetabular reamers supplied in the **NOVAE®** instrumentation set are identical in shape to the cup and therefore have a 3 mm cylinder that must be inserted right into the bone during the acetabular preparation.

To avoid any risk of imperfect preparation of the acetabulum and incomplete insertion of the definitive cup, we do not recommend using any other acetabular reamers than the ones provided with the **NOVAE®** instrument set.
The true bottom of the acetabulum is exposed by initially reaming with a small-sized reamer. Reaming at 45° is then performed using a reamer at least 2 mm smaller than the femoral head diameter.

The final reamer should be the same diameter as the selected cup diameter.

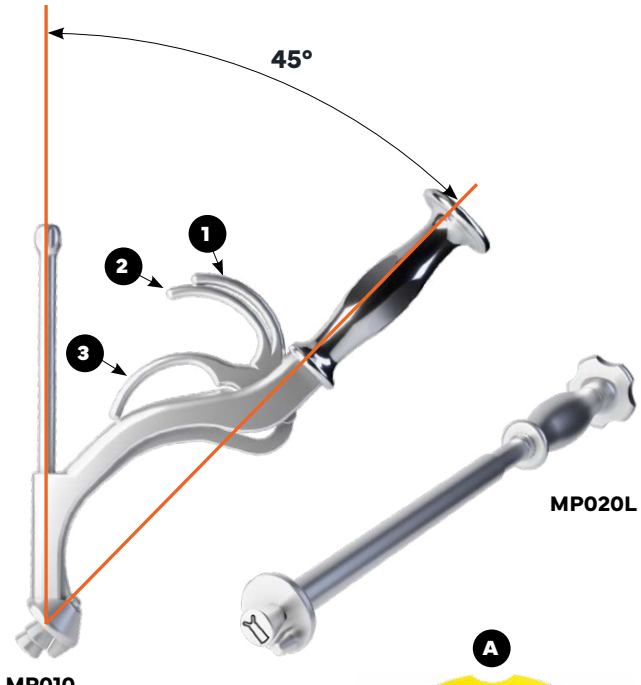
3 TRIALS

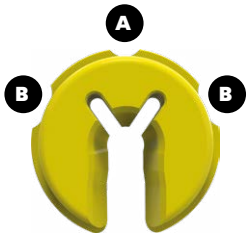
How to use the gripper / implant impactor handle

MP010 : The gripper/impactor handle is curved to adapt to the anterior hip approaches and minimally invasive surgeries. It is used to hold the trial cup and to guide and impact the definitive implant.

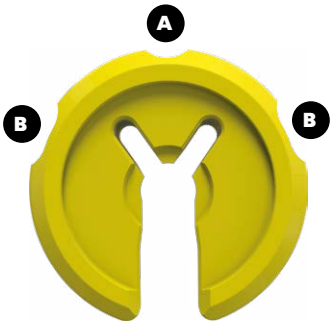
1. Position unlocked to maximum needed to put the "expanding" holder in place
2. Neutral position
3. Locked position: to be used to grip the trial cup and/or the definitive implant.

MP020L : Straight gripping/impactor handle and can be adapted to the different approach routes. It has an anvil that can be tightened or loosened to release or maintain the trial and definitive implant.





HOLDER SEEN FROM BELOW



HOLDER SEEN FROM ABOVE: SURFACE IN CONTACT WITH THE GRIPPER

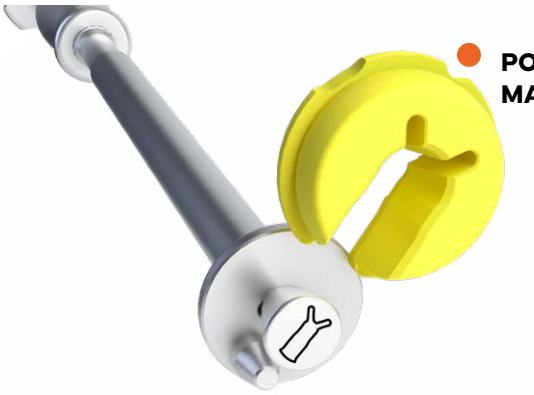
Use of the acetabular cup holder

When the expanding acetabular cup holder is used with the impacting gripper handle, it ensures that the trial and definitive acetabular cups are firmly gripped.

It has the following characteristics:

A A visualisation notch that need to be positionned relative to the marker on the edge of the **NOVAE®** cups.

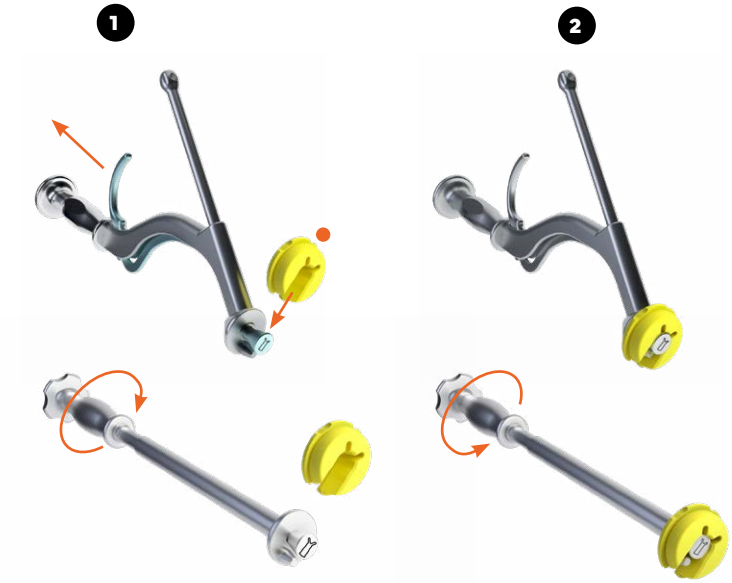
B 2 viewing windows used to identify how far the trial cup or definitive implant has been impacted into the acetabulum.



To set the expanding holder on the gripper / cup impactor handle (set to the diameter of the last reamer used) :

- **MP010 :** The gripper/impactor handle lever must be opened to its maximum length (position 1).
- **MP020L :** Loosened the anvil to insert the holder.

Use the positioning marker drawn on the gripper/impactor to mount the gripper at the front.



Positioning the trial acetabular cup

The trial acetabular cup is the same for all the **NOVAE®** cups.

Trial implant characteristics:

A A notch showing position of the flange for the **NOVAE® E TH** cup.
When putting it on the gripper handle, it must be positioned in front of the visualisation notch on the expanding holder.

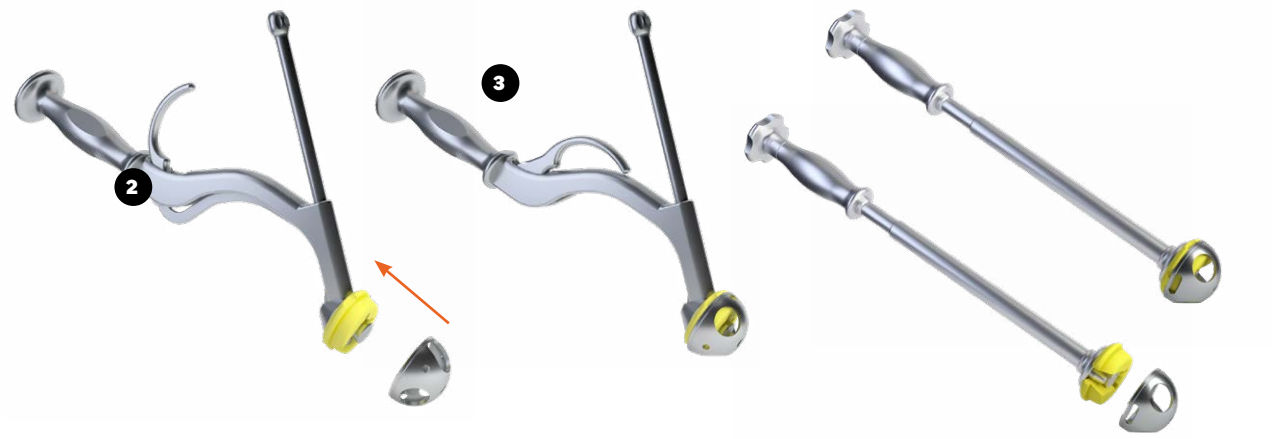
B A peripheral exterior groove materialising the 3mm cylinder that completes the hemisphere.

C Two holes showing peg position for acetabular cups with pegs.

D Lower opening to situate the acetabular teardrop position.

E Two upper engraved lines showing the position of the 2 flanges for the **NOVAE® COPTOS TH** cup.

F Position marker for **NOVAE® COPTOS TH** cup hook.



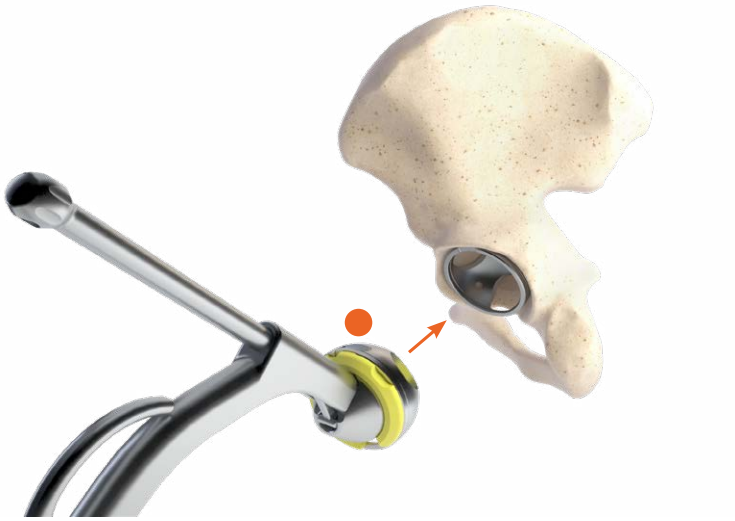
- **MP010:** Put the trial cup on the grip plate (position 2) then lock the handle by closing the lever (position 3).
- **MP020L:** Put the trial cup on the grip plate then lock the handle by tightening the anvil of the handle.

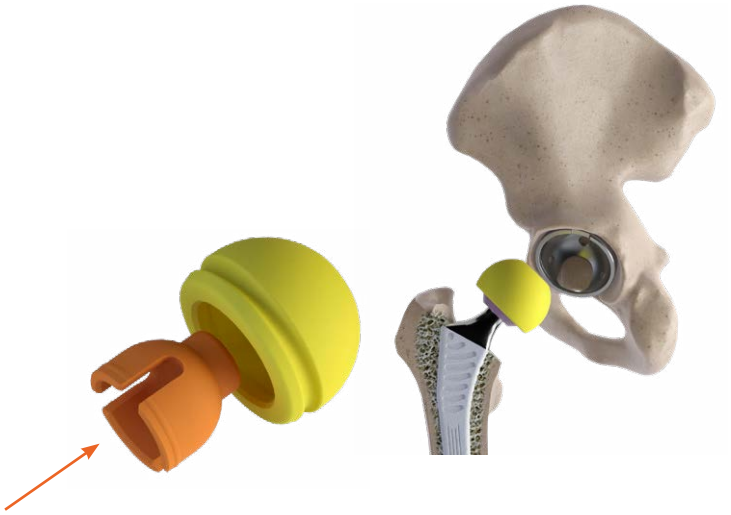
Impact this unit into the acetabulum respecting the orientation and anteversion determined during the pre-operative planning.

It is important to take the markers on the trial implant into consideration in accordance with the cup that will be implanted (markers A to E explained on the previous page).

The trial implant has an equatorial press-fit. If the trial implant behaves correctly in the acetabulum, the size of the definitive implant can be confirmed.

At this stage, reduction trials can be carried out in the trial implant.
For this, it just needs to be left in the acetabulum and the gripper/impactor handle removed.





Trial evaluation

The yellow trial liners are used with the Ø 28 mm heads. To perform trials with Ø 22.2 mm heads, a yellow trial liner must be combined with a Ø 22.2 / Ø 28 orange trial liner adaptor.

The trials can be carried out using the trial head or the definitive femoral head.

Mount the trial liner on the trial femoral head (or the definitive one on the stem or on the trial neck broach).
Then carry out the hip reduction by exercising axial traction of the leg and by pushing the liner into the bottom of the acetabular cup using the dual mobility impactor tip attached to its impactor handle.
Carry out tests for stability, angular range, and leg length.
Once the diameter and length of the neck have been determined, remove the trial liner.

Preparation of the definitive implant

The **NOVAE® SUNFIT TH**, **E TH** and **COPTOS TH** cups come with a disposable, pre-assembled polyethylene impaction plate compatible with standard implant holders (part of the VARANS02 instrumentation set).

This single-use plate is made of polyethylene. To use the curved gripper/impactor handle, this plate must be removed.

This operation is carried out in 3 steps and can be done with no contact on the implant (leaving it in its packaging):

1. Clip the extractor into the plate
2. Insert the pusher pin into the extractor
3. Bring the extractor to the pusher pin and remove the plate

4 NOVAE® SUNFIT TH IMPLANTATION

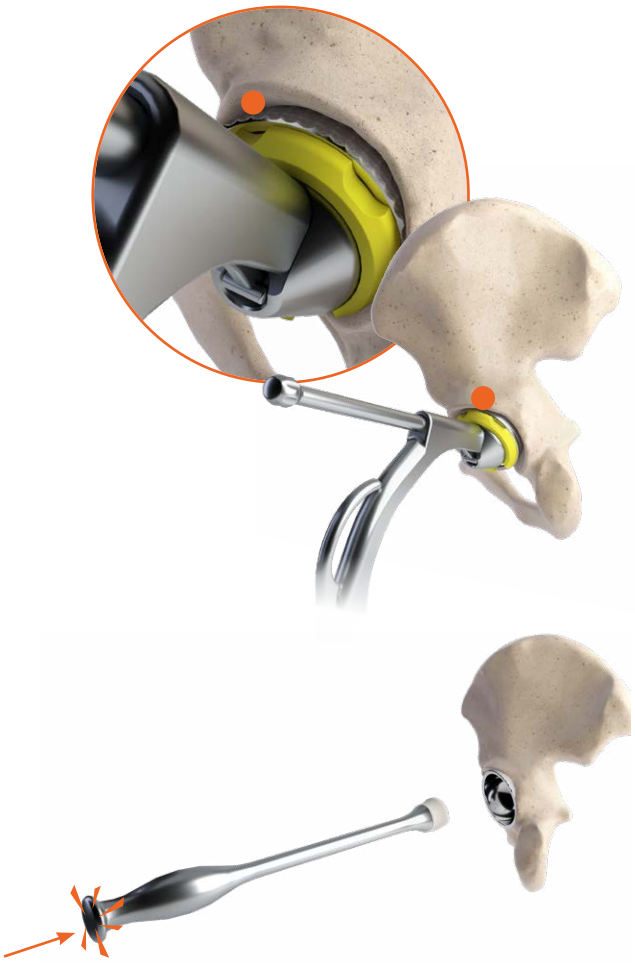
Mount the **NOVAE® SUNFIT TH** cup on the gripper/ impactor (already fitted with the right-size expanding holder for the definitive implant).

Present the **NOVAE® SUNFIT TH** cup in front of the acetabular cavity.
The notch on the implant gripper makes it possible to see the marker on the side of the implant that must be positioned towards the roof of the acetabulum.

The inclination/abduction of 45° and the anteversion (between 15 and 20°) should be checked prior starting impaction.
Proceed to the impaction of the implant and then open the handle to remove the impactor.
To complete impaction of the implant, the straight impactor can be used with the acetabular cup impactor tip.

Protect the polished surface with a sterile pad.

It is not recommended to correct the inclination/ abduction of the cup after impaction, however it must be fully seated in the acetabulum.
To ensure this, there is a notch in the cup impactor tip so that pressure can be put on its edge.



5 NOVAE® E TH OR COPTOS TH IMPLANTATION

The flanges of the **NOVAE® E TH** and **NOVAE® COPTOS TH** cups are pre-bent.

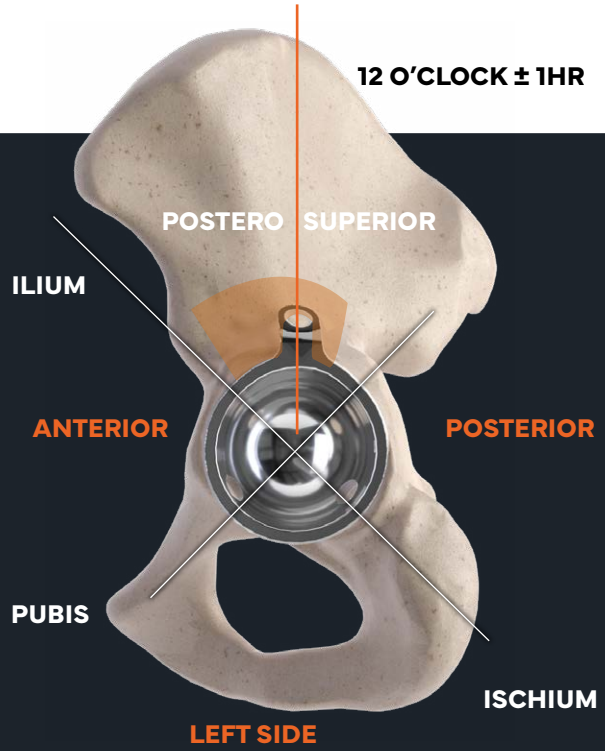
The angle of the curvature can be altered using the flange modeller included in the dedicated instrumentation set.

Mount the **NOVAE® E TH** cup (or **NOVAE® COPTOS TH** cup) on the gripper/impactor that is already fitted to the expanding holder that is the size of the definitive implant.

Present the cup in front of the acetabular cavity.

The notch on the acetabular cup grip makes it possible to see the marker on the side of the implant that must be positioned towards the roof of the acetabulum.

The inclination/abduction of 45° and the anteversion (between 15 and 20°) should be checked prior starting impaction.



Positioning the definitive cup

Example :
For a left side in a lateral view, the cup flange must be positioned at twelve o'clock, plus or minus one hour, so that the peg holes are respectively opposite the ischium and the pubis.
The flange or flanges (according to the cup chosen) are set against the iliac bone.

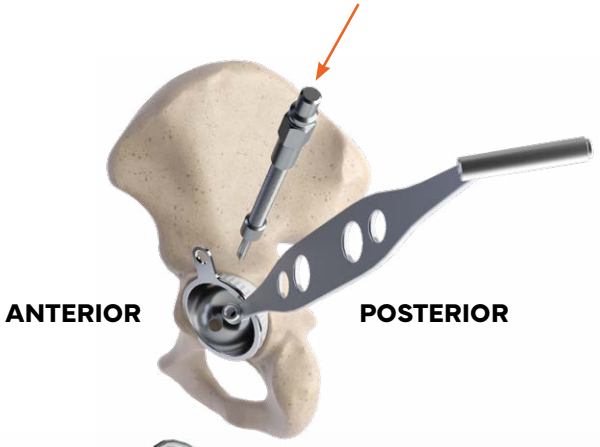
Impact the cup then open the lever to remove the impactor.

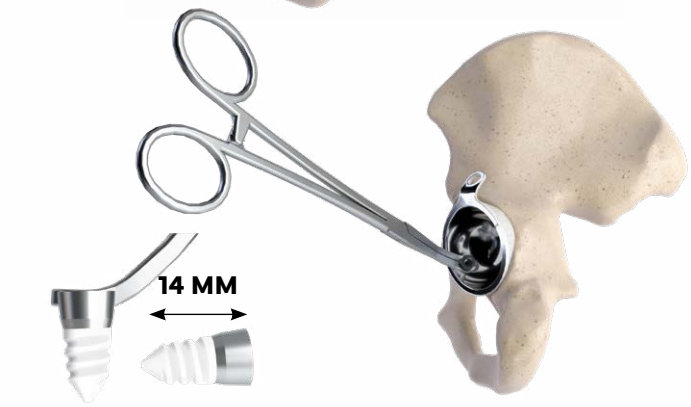
Pegs placement

The 2 pegs are sterile packaged with the **NOVAE® E TH** and Coptos TH acetabular cups.
Attach a flexible drill bit to the guide.
The two holes are prepared immediately afterwards.

To do this, position the guide correctly in the hole and drill to the stop piece of the flexible drill bit.
Hold the pegs with the peg-holder forceps.

A first peg is partly impacted then the second is put in place and both are pushed in alternately using a straight or curved handle.
The pegs must be fully seated and must not exceed the inner surface of the cup.





Drilling and screw placement

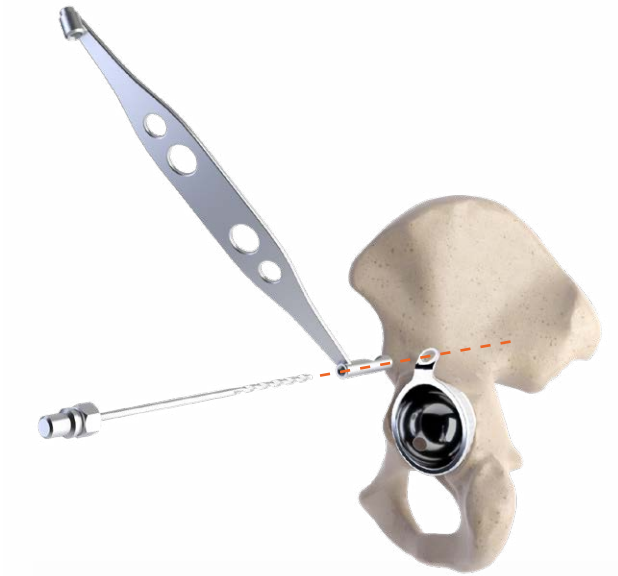
The Ø 3.2 mm hole(s) is (are) made using the drill bit guide oriented towards the acetabulum roof in the posterosuperior quadrant. The drill bit must be angled upwards (at 45° relative to horizontal) and backwards as slant as the iliac wing allows.

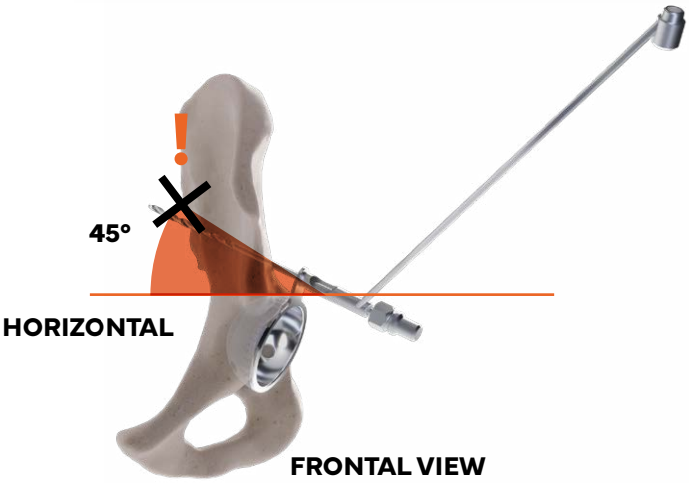
- Drill to the inner edge of the 2nd cortex
- The drill is taken out and replaced by the depth gauge.

The depth is read and 5 mm will be added for the length of the screw.
Two hands are needed to drill the second cortex: one pushing, one holding back.
The condition of the drill must be checked prior to use and a high rotation speed is recommended (about 1000 tr/min). Drilling must be done carefully, particularly at the second cortex.
It is sometimes useful to alter the angle of the drill bit after going through the first cortex.

The drilling angle is preserved until the screw is put in place.
The Ø 5 mm sterile self-tapping cortex screw can be inserted with a power drill bit and locking completed using a manual hex screwdriver.

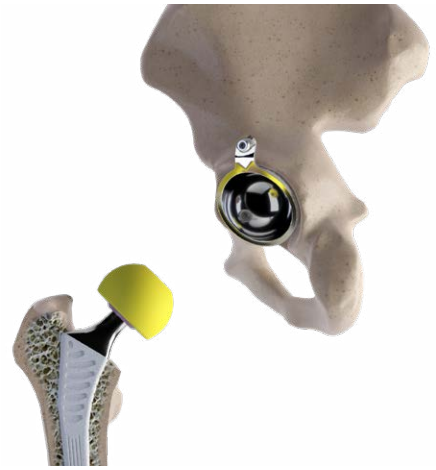
The pegs must be re-impacted after the screws are tightened.





Trial reduction

The trial reduction can be done in the definitive cup.
Mount the trial liner on the trial or definitive femoral head in place on the stem (or on the trial neck on the broach). Reduce the hip and test articular stability.
Then carry out the hip reduction by exercising axial traction of the leg and by pushing the liner into the bottom of the acetabular cup using the dual mobility impactor tip attached to its impactor handle. Carry out tests for stability, angular range, and leg length.
The definitive head will be chosen according to the results of these trials.
When the trials are completed, remove the trial implants (liner and head or just the liner) that are in place.



6 NOVAE® STICK IMPLANTATION

Two fixation options are available for the NOVAE® STICK cup:

- **A** Cemented directly in the acetabulum
- **B** Cemented in the **NOVAE® K E**

A Cemented directly in the acetabulum

The **NOVAE® STICK** cup comes with a loose single-use polyethylene impaction plate. Mount the disposable impactor on the gripper/impactor handle.

Put the cement at the back of the acetabulum then position the **NOVAE® STICK** cup in the acetabular cavity.
The inclination/abduction of 45° and the anteversion (between 15 and 20°) should be checked prior starting impaction.

Position the gripper (along with the disposable impactor that came with the cup) on the edge of the implant to hold it in place during cement polymerisation.

This impaction plate is not stuck into the cup to prevent micromovements of the cup in the cement while it is hardening.

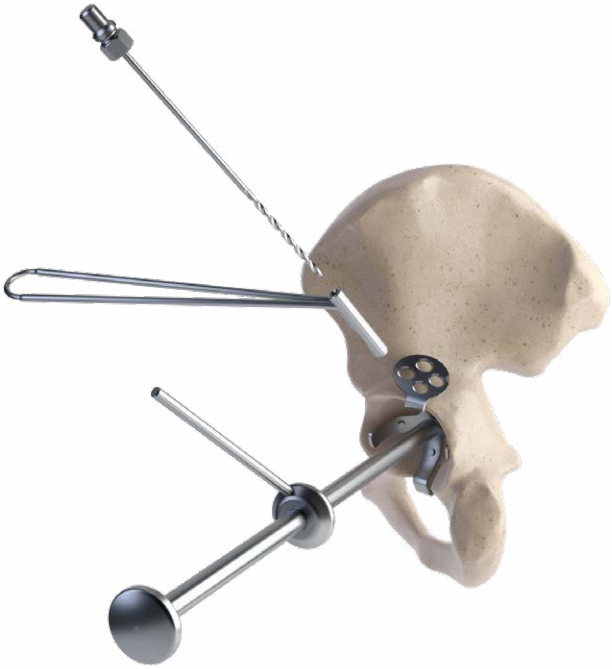
The single-use impactor also prevents cement coming into contact with the polished surface of the **NOVAE® STICK** cup.

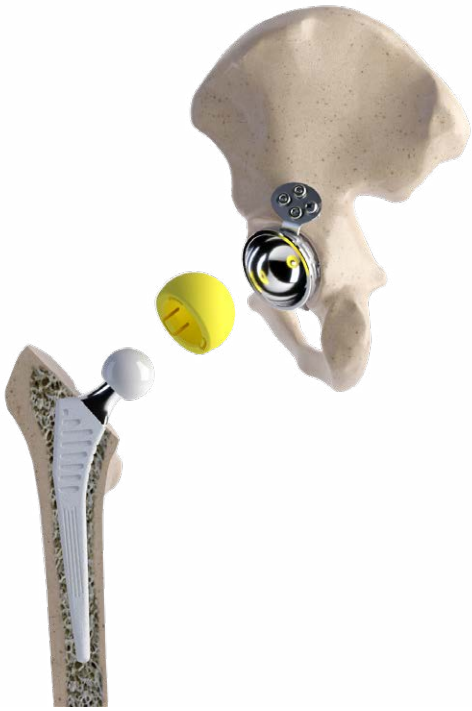
Once cement polymerisation is complete, remove the straight impactor handle and the impaction plate.

B Implantation into the NOVAE® K E cross-plate

Select and test the trial cross-plate that fits best to the anatomy of the acetabulum.
Bone grafts are positionned according to the importance of the bone defect.
The positionning shaft is screwed at the bottom of the cross plate and the positioning guide makes it possible to appreciate the required orientation.

It is important to keep the **NOVAE® K E** cross hook firmly held on the edge of the obturator foramen.
The upper plate is strongly applied while the screws are being screwed up. It is recommended to use a screw in every hole of the plate.
Cement the **NOVAE® STICK** cup into the cross-plate.





Trial reduction

The trial reduction is carried out in the definitive cup.
Mount the trial liner on the trial femoral head (or the definitive one on the stem or on the trial neck broach).

The trials can be carried out using the trial head or the definitive femoral head.

Mount the trial liner on the trial femoral head (or the definitive one on the stem or on the trial neck broach).

Then carry out the hip reduction by exercising axial traction of the leg and by pushing the liner into the bottom of the acetabular cup using the dual mobility impactor tip attached to its impactor handle.
Carry out tests for stability, angular range, and leg length.

The definitive head will be chosen according to the results of these tests.

When the tests are completed, remove the trial implants (liner and head or just the liner) that are in place.

7 ASSEMBLY OF THE LINER AND THE DEFINITIVE HEAD

ICJB E

There are two options:

A On table assembly

B In situ assembly

A On table assembly

Screw the black head supporting piece and the locking ring together centring them on the fork of the mobile liner impactor.
Hold the impactor vertically on the table.

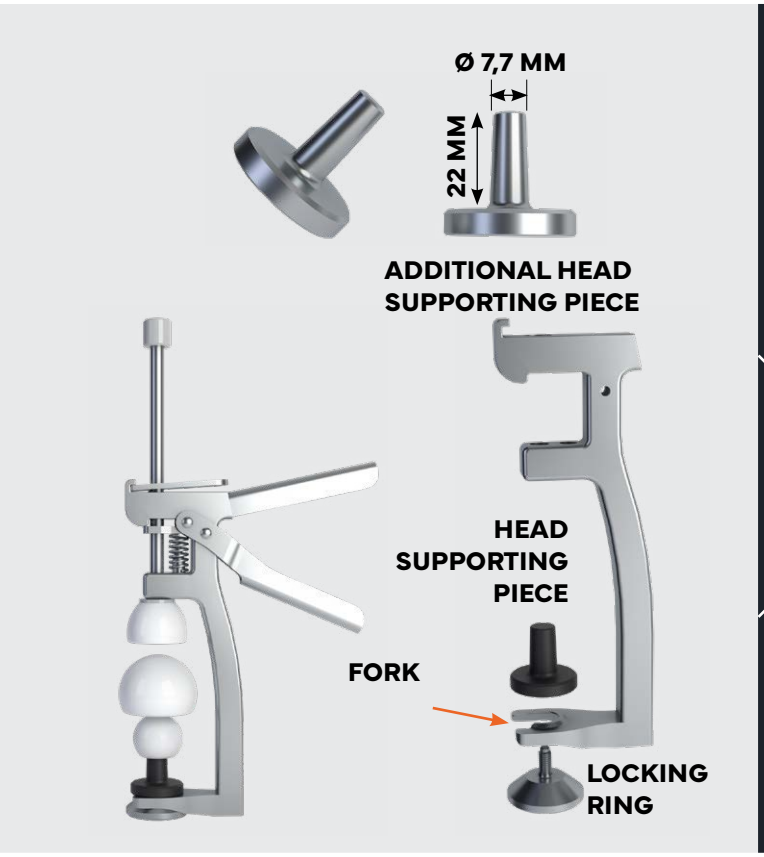
Avoid getting any liquids on the definitive head and definitive liner as this could make it impossible to reduce the head into the liner.

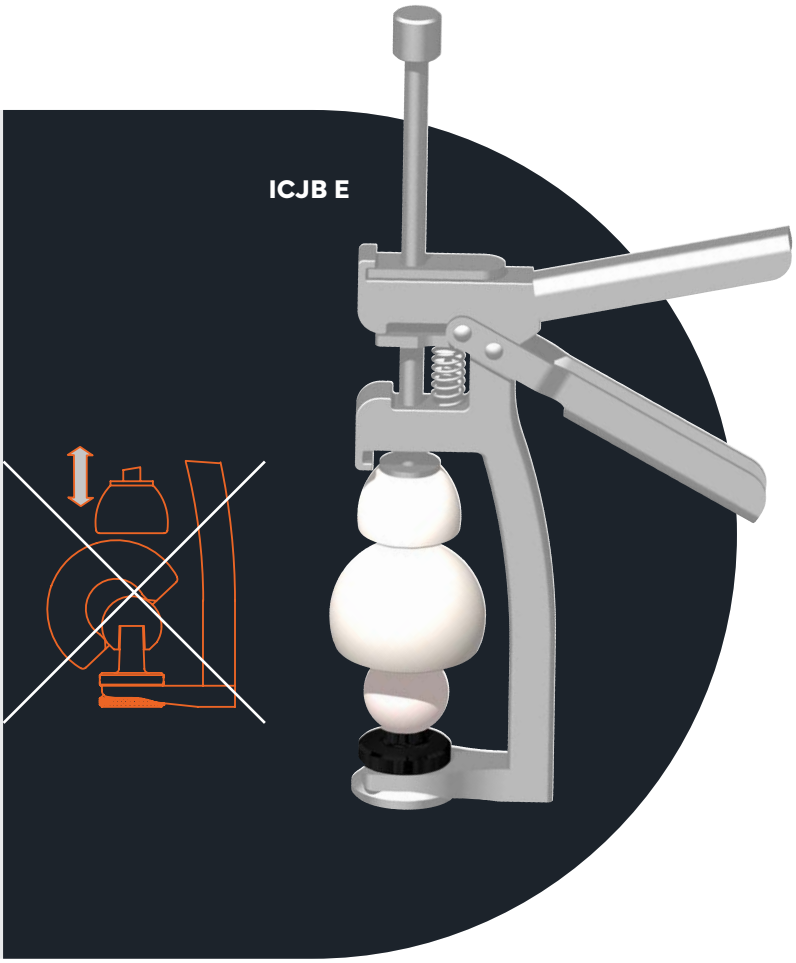
Place the head onto the head supporting piece and position the liner on the head.

A second supporting metallic piece is supplied in addition to the head supporting piece, for stems with a small morse taper.

Start to tighten the press to reduce the head into the liner whilst keeping the polyethylene liner in the axis of the impactor cone when the piston descends.

The head is fully lodged into the liner when the retention area has been passed, and when the head is fully mobile in the liner.





B In situ assembly

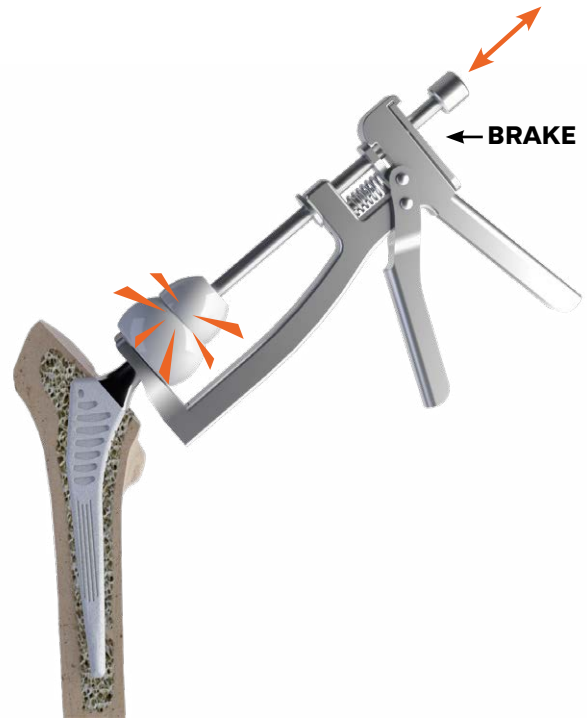
Position the impactor fork below the implant head (neck Ø 13 max).
Place and hold the liner in the axis of the neck at moment of full impaction (final air release).

Unlocking the impactor

Once the head and the liner are assembled, unlock the impactor by pressing on the brake.

Pull the stem back to free the liner.
Check mobility of the head in the polyethylene liner thoroughly after impaction.

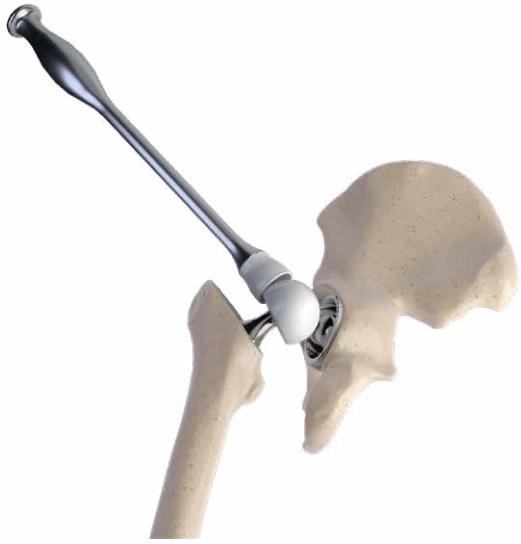
SERF denies any responsabilities in case of compatibility problems caused by implants made by other companies as we can not grant their compatibility.



CLICKER®

Place the femoral head on the cone and position the insert of the determined size on the centering device.
Start tightening the handle to reduce the head into the insert.
The insert is retained and will be centered automatically as the press is lowered, thanks to the the press.

To retrieve the head and insert assembly, lower the Clicker® carriage and retrieve the assembled implants. The head is perfectly impacted in the insert as soon as the retention zone is passed, this is materialized by the passage of «two overthicknesses».



8 IMPACTION AND DEFINITIVE REDUCTION

Assemble the impactor tip on the gripper/ impactor handle.

Position the femoral head assembly and liner in the cone of the definitive femoral stem, then proceed with impaction using the impactor tip with its impactor handle.

Then carry out the hip reduction by exercising axial traction of the leg and by pushing the liner into the bottom of the acetabular cup using the dual mobility impactor tip attached to its impactor handle.

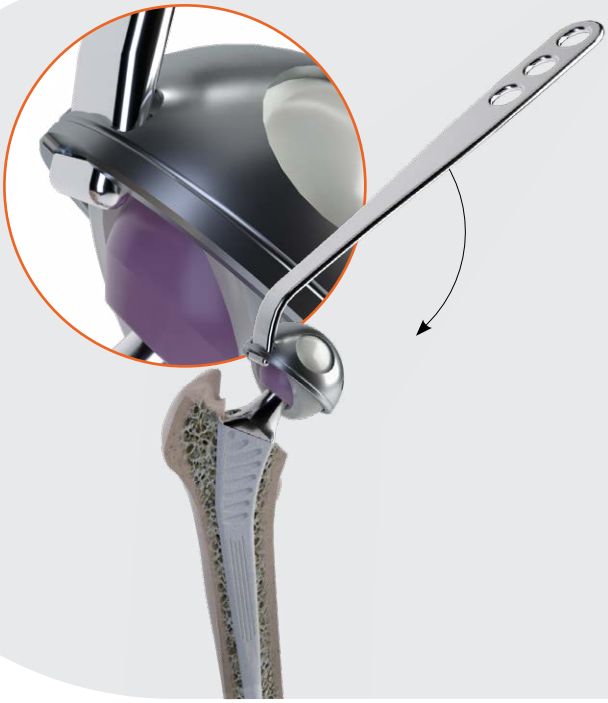
Carry out tests for stability, angular range, and leg length.

Revision cases

PEGS EXTRACTION FOR NOVAE® E TH AND NOVAE® COPTOS TH

A Screw the peg extractor into the thread in the peg until it is extracted.

B Take out the first peg and do the same to extract the second one.



EXTRACTION OF THE MOBILE LINER

1. Place the appropriately sized trial cup on the liner in place
2. Turn the liner so that the notch on it (point A on page 13 of this document) is exposed and is accessible.
   Insert the liner extractor into this notch.
3. Lever it to pull out the liner

Warning:

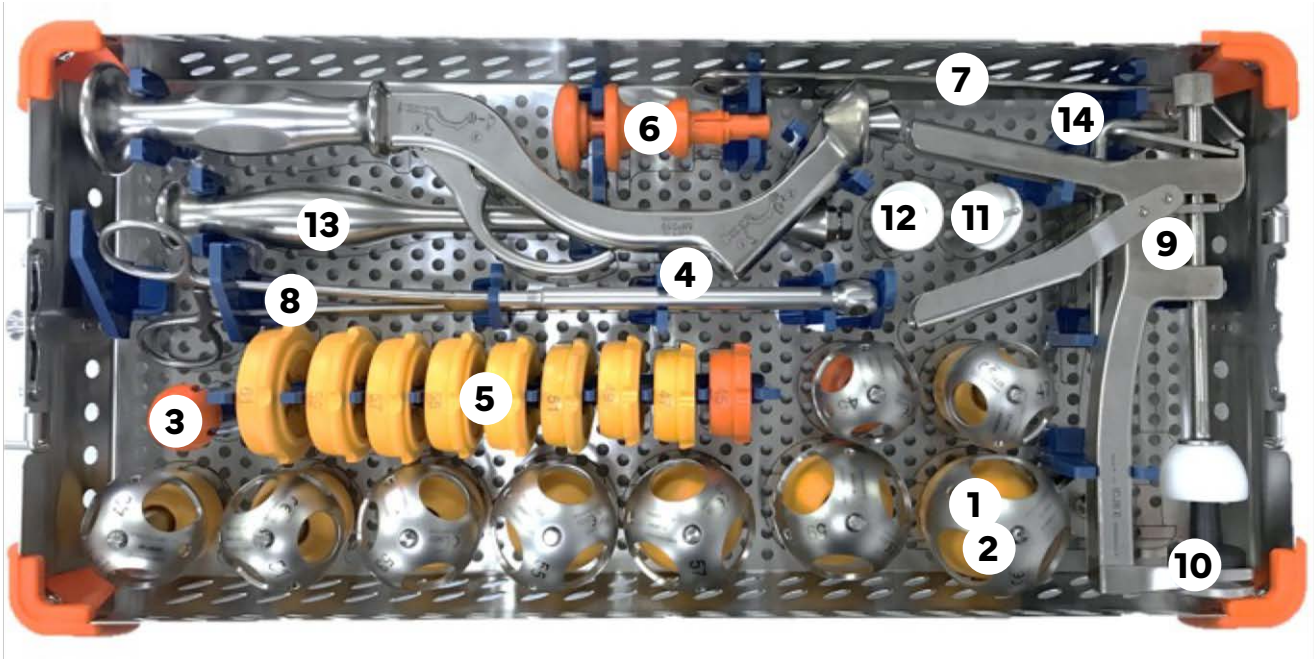
The insert is not re-sterilizable once removed and must be placed with the waste of care activities with infectious risks (according to the regulation in force).

INSTRUMENTATION

NOVAE® E TH, SUNFIT TH, COPTOS TH & STICK

VARANX01 - TRAY 1

N°	REFERENCES	DESIGNATION
1	IR45/22,2 to IR61/28	Retentive trial liners Ø45 to Ø61 for heads Ø22,2 and Ø28
2	GE007-45 to GE007-61	Ø45 to Ø61 trial cups
3	AR22-28	Retentive trial liner adapter Ø22.2 / Ø28
4	MP010 TIV009	Mini invasive handle Threaded stem for MP010 handle
5	PC-45 to PC-61	Ø45 to Ø61 cup holder adaptors
6	EXTPCJ	(PCJ) Disposable cup extractor
7	ECM 8	Dual mobility liner extractor
8	PPN E	Pegs forceps
9	OR ICJB E CLICKER	Liner head impactor Clicker liner head impactor (see tray 2)
10	COJB 75 M	Press support taper Ø7,5
11	EI016	Cup impactor
12	EI015	Liner inserter
13	MI 603	Impaction shaft
14	CA701	Hexagonal angled wrench Ø6



NB: There is a specific instrumentation set for Ø 41 to 43, & Ø 63 to 69 (VARANW01).

NOVAE® E TH, SUNFIT TH, COPTOS TH & STICK

VARANX01 - TRAY 2

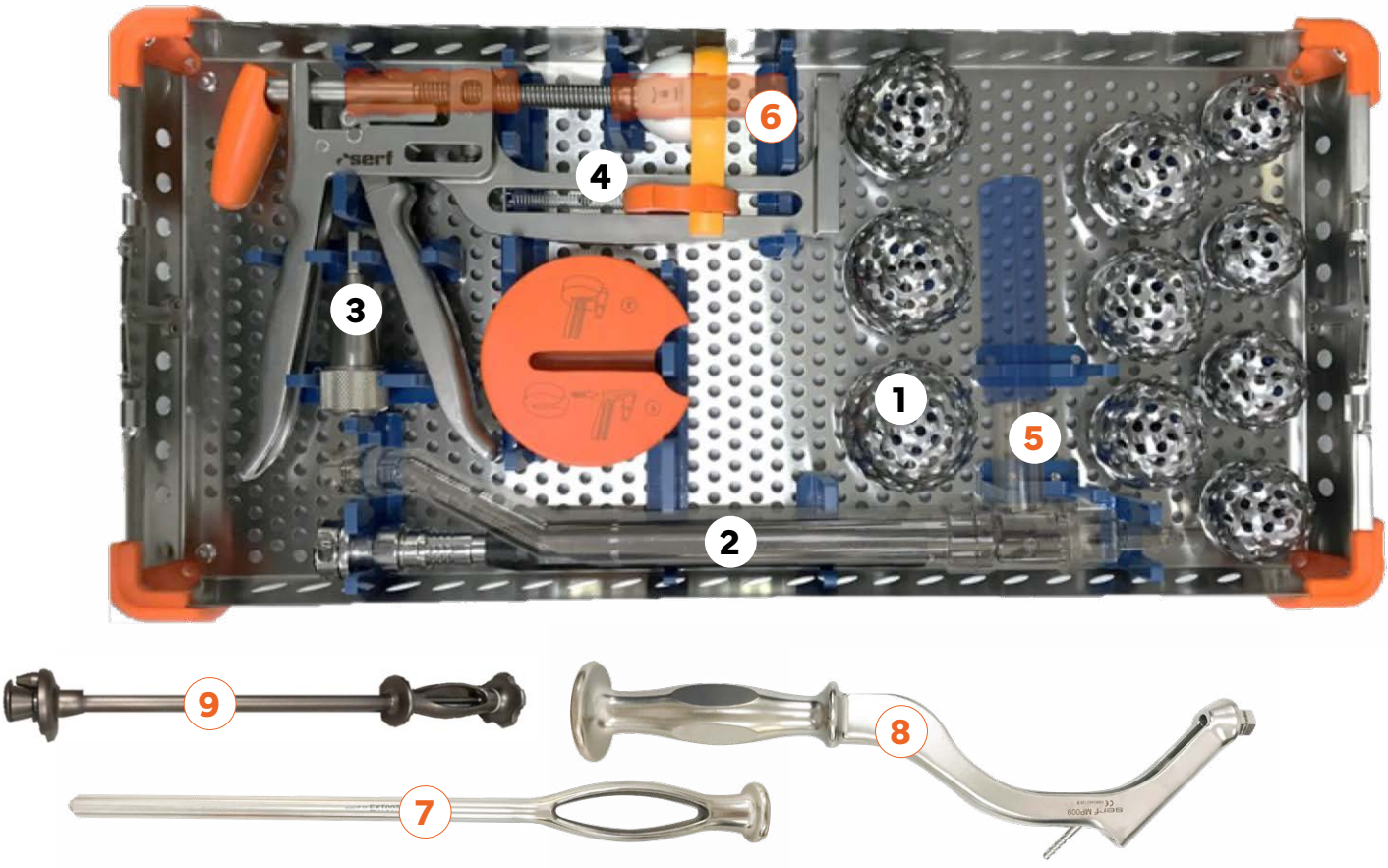
N°		REFERENCES	DESIGNATION	
1		FT 43 to FT 61	Ø43 to Ø61 reamers	
2	OR	TFE-2 TFT-AO	Reamer handle	
3		ET	Reamer adaptor	
4	OR	CLICKER ICJB E	Clicker liner head impactor Liner head impactor	

Optional additional instrumentation included in the tray:

5	TF001	Minimally invasive reamer handle	OPTION
6	JBG-3	ICJB E handle	OPTION

Optional additional instrumentation delivered in a separated bag:

7	EXT007	Trial cup extractor	OPTION
8	MP009	Minimally invasive gripper shaft	OPTION
9	MP020L	Straight gripper shaft	OPTION

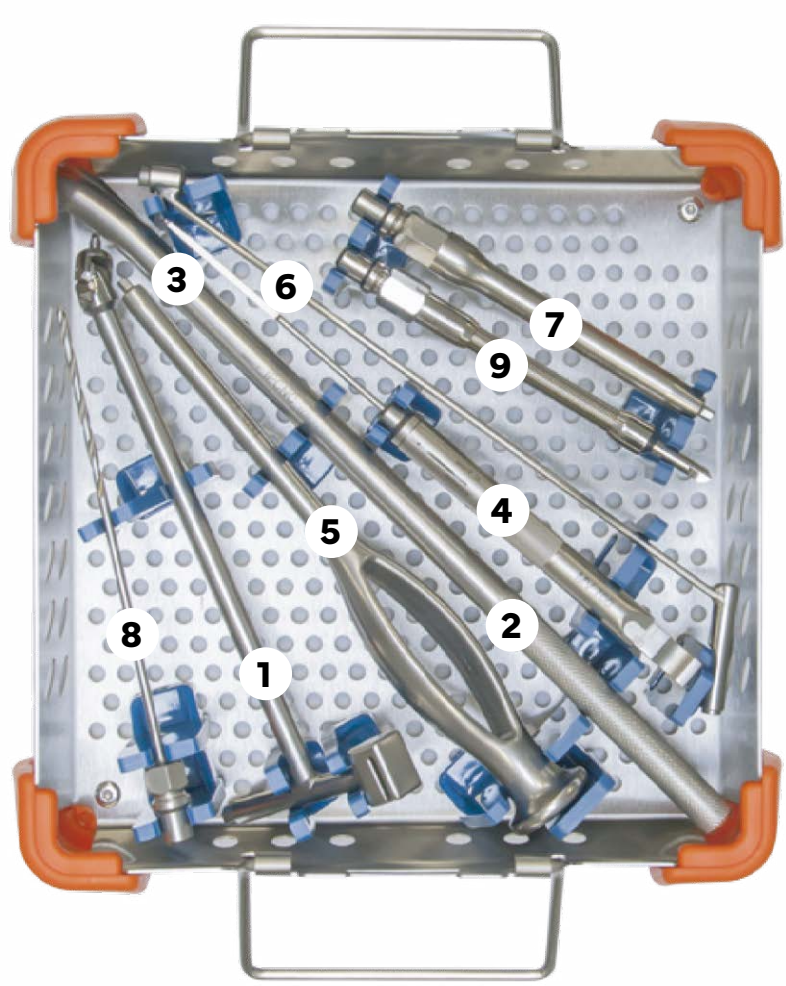


NOVAE® E TH & COPTOS TH

ADITIONNAL INSTRUMENTS PEGS AND SCREWS

VARAIY01

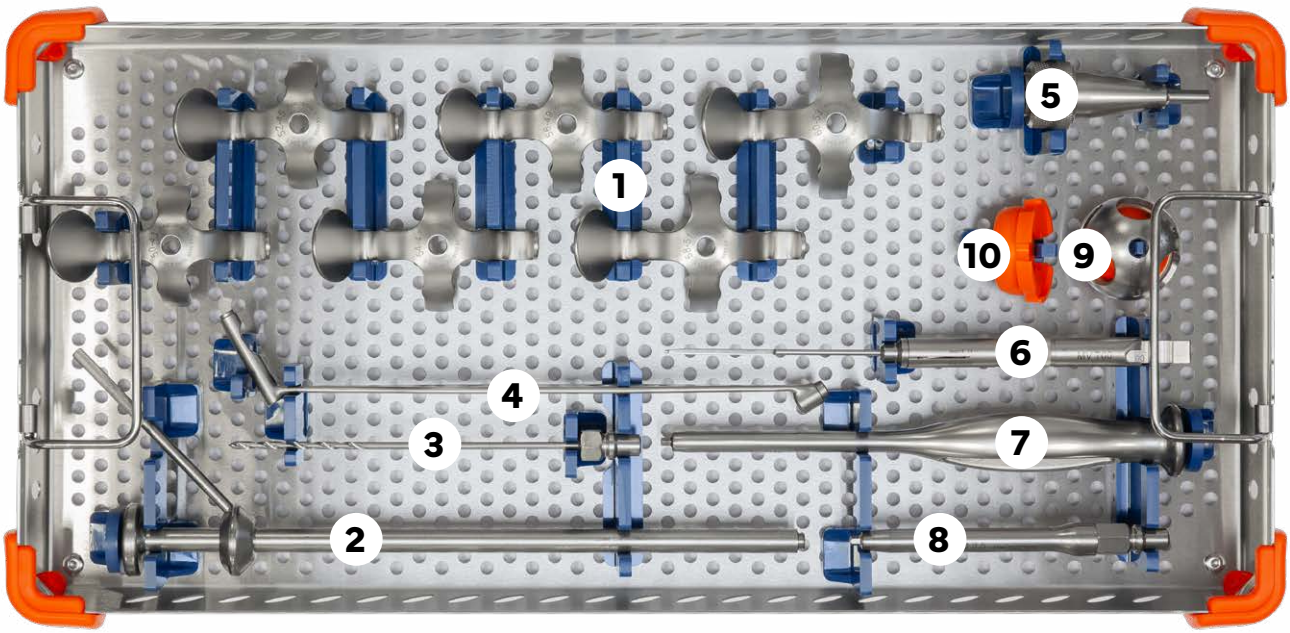
N°	REFERENCES	DESCRIPTION
1	EPMP6	Peg extractor / 6 mm hex wrench / Flange modeller
2	IPCN	Straight peg impactor
3	IPCNC	Curved peg impactor
4	MV700	Depth gauge
5	TMA 3,5 E	3.5 mm manual hex screwdriver
6	GM 3,2-5 E	Drilling guide for Ø 3.2 mm drill bit
7	TMO 3,5	3.5 mm motorised hex screwdriver
8	F 3,2-150 E	Ø 3.2 mm (lg 150) drill bit with snap lock
9	MF 5 E	Ø 5 mm flexible drill for studs



K E INSTRUMENTS & DRILLING KIT

VARAKF01

N°	REFERENCES	DESCRIPTION
1	ESK E 50/43 to 60/53	Neutral trial cross plate 50/43 Neutral trial cross plate 52/45 Neutral trial cross plate 54/47 Neutral trial cross plate 56/49 Neutral trial cross plate 58/51 Neutral trial cross plate 60/53
2	MCFC 2	Cross plate handle (implant and trial)
3	F 3,2-150 E	Ø 3.2 mm drill (lg 150) with snap-lock mechanism
4	GM 3,2-5 E	Drilling guide for Ø 3.2 mm drill bit
5	ET	Lock mechanism
6	MV 700	Depth gauge
7	TMA 3,5 E	3.5 mm manual hex screwdriver
8	TMO 3,5	3.5 mm motorised hex screwdriver
9	IE006 43/22.2 GE007-43	Extra trial liner for NOVAE® STICK 43/22.2
10	PC-43	Expander cup holder



ACCESS TO THE DIGITAL INSTRUCTION FOR USE

For each type of implant, **SERF** provides you with specific, regularly updated digital Instructions for Use that can be searched, downloaded, and printed according to your needs.
A hard copy of these Instructions for Use can be sent to you within 7 calendar days, without fee, through a simple request to **SERF**.

In these Instructions for Use, you will find not only the regulatory information and technical features of our implants, but also valuable information on the indications, contraindications, compatibility between implants, permissible examinations and those to strictly avoid, etc.

These digital Instructions for Use, in Adobe® Acrobat® PDF format, can be accessed and downloaded in two ways:

- using a QR code on the implant's label, which can be read with a smartphone or tablet (internet connection required; 3G/4G, Wifi, etc.) and a suitable reading app (available to download for free from Google Play, Apple® Appstore and Windows® Store depending on the model of device used)
- using an internet connection on a computer, smartphone, or tablet, by typing the URL address indicated near the QR code directly into your usual internet browser.

Here below is the QR code and URL address of the dematerialized IFU covering the range of **NOVAE®** acetabular coponent presented in this document:

http://doc.serf.fr/0920.pdf

Acrobat Reader DC Operating System required

Windows

- 1.5 GHz processor or faster
- Windows Server 2008 R2 (64 bits), 2012 (64 bits), 2012 R2 (64 bits)† or 2016 (64 bits); Windows 7 SP1 (32 and 64 bits), Windows 8, 8.1 (32 and 64 bits)† or Windows 10 (32 and 64 bits)
- 1 Gb of RAM
- 380 Mb of free disk space
- 1024x768 screen resolution¬
- Internet Explorer 11

MacOS

- Intel processor
- Mac OS X v10.11, macOS v10.12, macOS v10.13 or macOS v10.14*
- 1 Gb of RAM
- 380 Mb free disk space
- 1024x768 screen resolution
- Safari 9.0, 10.0 or 11.0 (The plug-in for Safari is supported only by 64-bit systems with an Intel processor).

Mobile applications

- Adobe Acrobat Reader: iOS, Android, Windows Phone
- Adobe Scan: iOS, Android
- Adobe Fill & Sign: iOS, Android

NOTES

Unless they are specifically identified as "not CE marked", all the medical devices mentioned in this document are CE marked in accordance with Directive 93/42/EEC and its amendments and/or with Regulation (EU) 2017/745 (the devices covered by one and/or the other regulatory referential are indicated in the IFU).

The medical devices mentioned in this document are class I, Ir, IIa, IIb, III devices. Class I, Ir, IIa, IIb, III medical devices are marked CE 0459 by GMED.

Before using any SERF product, make sure to read the product(s) instructions for use in force, the only document containing all the information required for CE marking of the product(s).

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