

# **NOVAE**<sup>®</sup>

**Dual Mobility Cups** 

# - SURGICAL TECHNIQUE



# Content

Presentation of the Novae® acetabular cups 4 The range of implants 7 Implants references 8 Surgical technique 10 Instruments sets 20 Access to dematerialised Instructions For Use 24

# Presentation of the Novae® acetabular cups

The **Novae**<sup>®</sup> range of acetabular cups is intended for primary total hip arthroplasty and revision cases, with and without cement.

**Novae**<sup>®</sup> 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:



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 replacemendual mobility cup is reduced mobility cup is reduced of the mobile liner is a The metal or cerce a The femoral stement that is preferably to a shine without because of the n contact between and the prosthetic the different implants range are:	ent with a <b>Novae</b> <sup>®</sup> made up of the following: forged stainless steel in polyethylene amic femoral head that must have a neck smooth and polished of any sharp corners ormal but repetitive the polyethylene liner ic neck.		
Designation	Implant type	Materials	N.
Novae® SunFit TH	Cementless cup for primary THA	X18M25W (ISO5832-1) stainless steel and titanium spray + HA coating	1
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 Stainless steel pegs 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 Stainless steel pegs with alumina coating	
Novae® Stick	Cemented cup	Stainless steel X18M25W (ISO5832-1)	
Novae® K E	Kerboull cross-plate intended to be used with Novae® Stick cup	Stainless steel X18M25W (ISO5832-1)	_
CI E liner	Dual mobility liner (common to all Novae <sup>®</sup> cups)	Polyethylene (UHMWPE ISO5834-2)	
VCI screw	Cortical screw Ø 5 mm	Stainless steel X18M25W (ISO 5832-1)	-

### Novae<sup>®</sup> acetabular cup characteristics

All of the **Novae**<sup>®</sup> 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 cups without cement 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  $150\pm30 \,\mu$ m) and HA coating (thickness  $70\pm20 \,\mu$ m), on the outer surface of the cups without cement.

All of the **Novae**<sup>®</sup> acetabular cups without cement come with their pre-assembled polyethylene cup gripper (single use) and the **Novae**<sup>®</sup> **Stick** cup comes with a disposable cup impactor (also single use).





### Novae<sup>®</sup> Sunfit TH

The **Novae® Sunfit TH** cup is an acetabular implant without cement 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<sup>®</sup> E TH

The **Novae**<sup>®</sup> **E TH** cup is an acetabular implant without cement intended for primary total hip replacement (THR).

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<sup>®</sup> Coptos TH

The **Novae® Coptos TH** cup is an acetabular implant intended for acetabular reconstructions without cement. 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.

7

### Novae<sup>®</sup> 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® Stick** E cross-plate.



### Croix Novae® K E

The **Novae**<sup>®</sup> **K E** cross-plate is intended to recreate a background necessary for the implantation of a **Novae**<sup>®</sup> **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 centre 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.

# The range of implants



Novae<sup>®</sup> SunFit TH Ø 43 to 69 mm



**Novae® E TH** Ø 41 to 69 mm



Novae<sup>®</sup> Coptos TH Ø 43 to 69 mm



**Novae® K E** Size 50/43 to 60/53 mm Right & left sides



Novae<sup>®</sup> Stick Ø 43 to 63 mm

	CIE liner Thickness in mm	
Size	Head 22.2 mm	Head 28 mm
CI 41 E	6.1	/
CI 43 E	6.9	/
CI 45 E	7.9	/
CI 47 E	8.9	6.1
CI 49 E	9.9	7
CI 51 E	10.9	8
CI 53 E	11.9	9
CI 55 E	12.8	9.9
CI 57 E	13.8	10.9
CI 59 E	14.8	11.9
CI 61 E	15.8	12.9
CI 63 E	16.8	13.9
CI 65 E	17.8	14.9
CI 67 E	18.8	15.9
CI 69 E	19.8	16.9

9

The liners are compatible with all of the **Novae**<sup>®</sup> 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.

# Implants references



Novae<sup>®</sup> SunFit TH

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



### Novae® E TH

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



### Novae<sup>®</sup> Coptos TH

S	ize	Designation	References
4	43*	COPTOS 43 TH	RM45360001
4	45	COPTOS 45 TH	RM45360002
4	47	COPTOS 47 TH	RM45360003
4	19	COPTOS 49 TH	RM45360004
Ę	51	COPTOS 51 TH	RM45360005
5	53	COPTOS 53 TH	RM45360006
Ę	55	COPTOS 55 TH	RM45360007
Ę	57	COPTOS 57 TH	RM45360008
Ę	59	COPTOS 59 TH	RM45360009
ć	51	COPTOS 61 TH	RM45360010
6	3*	COPTOS 63 TH	RM45360011
6	5*	COPTOS 65 TH	RM45360012
6	7*	COPTOS 67 TH	RM45360013
6	9*	COPTOS 69 TH	RM45360014



### Ø 5 mm cortical screws

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

\*Optional sizes available on request with a specific instrumentation set



### Novae® Stick

Size	Designation	References
43*	NOVAE STICK 43	RM49010000
45	NOVAE STICK 45	RM49010001
47	NOVAE STICK 47	RM49010002
49	NOVAE STICK 49	RM49010003
51	NOVAE STICK 51	RM49010004
53	NOVAE STICK 53	RM49010005
55	NOVAE STICK 55	RM49010006
57	NOVAE STICK 57	RM49010007
59	NOVAE STICK 59	RM49010008
61	NOVAE STICK 61	RM49010009
63*	NOVAE STICK 63	RM49010010



### Novae® K E

Left side	References	Right side	References
K E 50/43 G	RM48010150	K E 50/43 D	RM48010050
K E 52/45 G	RM48010152	K E 52/45 D	RM48010052
K E 54/47 G	RM48010154	K E 54/47 D	RM48010054
K E 56/49 G	RM48010156	K E 56/49 D	RM48010056
K E 58/51 G	RM48010158	K E 58/51 D	RM48010058
K E 60/53 G	RM48010160	K E 60/53 D	RM48010060



Insert 22.2	Références
CI 41/22,2 E*	RM51100001
CI 43/22,2 E*	RM51100002
CI 45/22,2 E	RM51100003
CI 47/22,2 E	RM51100004
CI 49/22,2 E	RM51100005
CI 51/22,2 E	RM51100006
CI 53/22,2 E	RM51100007
CI 55/22,2 E	RM51100008
CI 57/22,2 E	RM51100009
CI 59/22,2 E	RM51100010
CI 61/22,2 E	RM51100012
CI 63/22,2 E*	RM51100013
CI 65/22,2 E*	RM51100014
CI 67/22,2 E*	RM51100015
CI 69/22,2 E*	RM51100016

 $^{\ast}\mbox{Optional sizes}$  available on request with a specific instrumentation set



# Surgical technique

## **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.

### 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**<sup>®</sup> 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.

### Trials

### How to use the gripper / implant impactor handle

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.

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

### 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 visualisation notch that need to be positionned relative to the marker on the edge of the **Novae**<sup>®</sup> cups

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

Holder seen from above: surface in contact with the aripper

A

B

Holder seen from below

A

B

To set the expanding holder on the gripper /cup impactor handle (set to the diameter of the last reamer used), the gripper/impactor handle lever must be opened to its maximum length (position 1)

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



Positioning marker

### Positioning the trial acetabular cup

The trial acetabular cup is the same for all the **Novae**<sup>®</sup> cups.

Trial implant characteristics:

- 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 3 mm cylinder that completes the hemisphere
- Two holes showing peg position for acetabular cups with pegs
- D Lower opening to situate the acetabular teardrop position
- Two upper engraved lines showing the position of the 2 flanges for the Novae<sup>®</sup> Coptos TH cup
- Position marker for Novae® Coptos TH cup hook





Put the trial cup on the grip plate (position 2) then lock handle by closing the lever (position 3)

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 using the forceps (use the peripheral groove to grip).

### Preparation of the definitive implant

#### The Sunfit TH, Novae® 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):

- Clip the extractor into the plate
- 2 Insert the pusher pin into the extractor
- Bring the extractor to the pusher pin and remove the plate

### 4 SunFit TH implantation

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

Present the **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<sup>®</sup> E TH or Coptos TH implantation

The flanges of the Novae® E TH and 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 **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.

#### 12 o'clock <u>+</u> 1hr

### 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  $\emptyset$  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 2<sup>nd</sup> 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  $\emptyset$  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.



Front view

17

### **Trial reduction**

6

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.

### Novae<sup>®</sup> Stick implantation

Two fixation options are available for the **Novae® Stick** cup:

- Cemented directly in the acetabulum
- Cemented in the K E cross plate

### 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 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 **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.





There are two options: On table assembly In situ assembly

### On table assembly

Screw the black head supporting piece and the locking ring together centring them on the fork of the compression gun. 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.



Head supporting piece

### In situ assembly

Position the impactor fork below the implant head (neck  $\emptyset$  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.



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.



# Pegs extraction for Novae<sup>®</sup> E TH and Coptos TH

- Screw the peg extractor into the thread in the peg until it is extracted.
- Take out the first peg and do the same to extract the second one.

### Extraction of the mobile liner

- Place the appropriately sized trial cup on the liner in place
- Turn the liner so that the notch on it (point A on page 11 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 liner is not reusable once removed



## Instruments sets

Novae  $^{\rm R}$  E TH, SunFit TH, Coptos TH & Novae  $^{\rm R}$  Stick - VARANXO1 tray 1

NO.	Reference	Description
•	IE006 45/22.2 to IE006 61/28	Trial liners - Ø 45 to 61 / 22.2 and 28 mm
•	GE007-45 to GE007-61	Ø 45 to 61 mm trial cups
2	ADA22-28	Trial liner adaptor Ø 22.2 / Ø 28
3	MP010	Gripper/impactor handle for implant and template
	TIV009	Orientation stem for impactor handle
4	PC-45 to PC-61	Expander cup holder
5	EXTPCJ	Disposable cup holder extractor (PCJ)
6	ECM 8	Dual mobility liner remover
1	PPN E	Pegs forceps
8	ICJB E	Mobile liner impactor and head supporting piece
9	COJB 75 M	Metal support taper for small morse taper
10	EI016	Impactor tip for bottom and side of the cup
	EI015	Dual mobility liner impactor tip
12	MI 603	Gripper /impactor handle tip/ PCJ
13	CA701	Offset hex wrench



NB: There is a specific instrumentation set for  $\emptyset$  41 to 43,  $\emptyset$  63 to 69 and  $\emptyset$  71 and 73.

# Instruments sets

Novae® E TH, SunFit TH, Coptos TH & Novae® Stick - VARANXO1 Tray 2

NO.	Reference	Description
0	FT 43 to FT 61	Acetabular reamer Ø 43 to 61
2	TFE-2 or TFT-AO	Snap fit acetabular reamer handle
3	ET	Reamer adaptator



# Additional instruments sets

Novae® E TH and Coptos TH - VARAIYO1 Pegs and screws

NO.	Reference	Description
0	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
0	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



# Additionnal instruments sets

K E instruments & drilling kit - VARAKFO1

NO.	Reference	Description
0	RA90280050 RA90280052 RA90280054 RA90280056 RA90280058 RA90280060	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	RA90460002	Cross plate handle (implant and trial)
3	RA90350001	Ø 3.2 mm drill (lg 150) with snap-lock mechanism
4	RA90410029	Drilling guide for Ø 3.2 mm drill bit
5	RA90270002	Lock mechanism
6	RA90450030	Depth gauge
1	RA90710040	3.5 mm manual hex screwdriver
8	RA90710035	3.5 mm motorised hex screwdriver
9	RA90190701 RA90390943	Extra trial liner for Novae® Stick 43/22.2
10	RA90590143	Expander cup holder



# Access to the dematerialised Instructions For Use

SERF offers, for each type of implant, dematerialized Instructions for Use (IFU) regularly updated, and easy to download and to print according to your needs.

The corresponding notice can be sent to you in printed form within 7 calendar days. You will find in these IFU not only the regulatory information and technical specifications of our implants, but also valuable information on indications, contraindications, and compatibilities between implants, etc.

These dematerialized instructions, provided in PDF format, are available and downloadable via two ways:

- from a QR code on the packaging of the implant, which can be read using a smartphone or tablet (requires Internet connection, 3G / 4G, WiFi ...) and an application appropriate reading (available)
- for free download on Google Play, Apple<sup>®</sup> AppStore and Windows<sup>®</sup> Store according to the device used) with an Internet connection via a PC, smartphone or tablet, typing directly the URL address written near the QR code, to your usual Internet browser's,.

Here below is the QR code and URL address of the dematerialized IFU covering the range of **Novae**<sup>®</sup> acetabular coponent presented in this document:



http://doc.serf.fr/0910.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: HYPERLINK "https://itunes.apple.com/fr/app/adobe-reader/id469337564?mt=8" iOS, HYPERLINK "https://play.google. com/store/apps/details?id=com.adobe.reader&hl=fr" Android, HYPERLINK "http://www.windowsphone.com/s?appid=134e363e-8811-44be-b1e3-d8a0c60d4692" Windows Phone
- Adobe Scan: HYPERLINK "https://itunes.apple.com/fr/app/adobe-scan/id1199564834?mt=8" iOS, HYPERLINK "https://play.google.com/store/apps/
  details?id=com.adobe.scan.android&hl=fr" Android
- Adobe Fill & Sign: HYPERLINK "https://itunes.apple.com/fr/app/id950099951" iOS, HYPERLINK "https://play.google.com/store/apps/
  details?id=com.adobe.fas&hl=fr" Android



# Notes

	HIVE MEET
8.555	



# Notes



# Notes





All the medical devices in this document are CE marked according to Directive 93/42/CEE and its amendments, unless specifically identified as "not CE marked".

The medical devices mentioned in this document are devices of class I, IIa, IIb, and III.

Class IIa, IIb, and III medical devices carry CE mark 0459 with GMED.

Before using a SERF product, please refer to the instruction leaflet and to the surgical technique. Check the labels and product leaflets for the complete list of indications, contra-indications, risks, warnings, precautions, and instructions for use.

©2019 SERF. All rights reserved. Novae® is a trademark of SERF.

Distributed by





85 Avenue des Bruyères 69150 Décines-Charpieu - France Tel. +33 (0)4 72 05 60 10

DESIGN \ HARVEST.AGENCY