

Plasmafit™ Pro Acetabular Cup System

Surgical Technique



Aesculap Orthopaedics

Plasmafit™ Pro Acetabular Cup System

Surgical Technique

Table of Contents

I. Indications, Warning and Contraindications	3
II. System Overview	4
III. Surgical Technique	5-7
1. Acetabular Preparation	5
2. Trial Cup Insertion	5
3. Acetabular Cup Insertion	6
4. Additional Screw Fixation	7
5. Trial Liner Insertion and Final Liner Insertion	7
IV. Implant Overview	8
V. Instrument Overview	9-13

I. Indications, Warning and Contraindications

Indications for Use:

The Plasmafit Pro Acetabular Cup System and Vitelene™ Insert are intended for use with existing Aesculap femoral heads and femoral stems to replace the hip joint.

The devices are intended for:

- Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head and nonunion of previous fractures of the femur.
- Patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral epiphysis
- Patients suffering from disability due to previous fusion
- Patients with acute femoral neck fractures

Plasmafit Pro Acetabular Cup System and Vitelene Insert are intended for cementless applications.

Warning:

Only Ti plasma sprayed components should be implanted without cement. All other devices are designed for use with bone cement.

Contraindications:

Contraindications include, but are not limited to:

- Presence of fever, infection or inflammation (systemic or localized)
- Morbid obesity
- Pregnancy
- Mental illness or drug abuse
- Severe osteopenia (or any medical or surgical condition) which would preclude potential benefits of implants
- Suspected or documented metal allergy or intolerance
- Mixing of implant components from other manufactures
- Any case not listed in the indications; and
- Patients unwilling or unable to follow postoperative instructions
- Skeletal immaturity

Please refer to the instructions for use for important product information, including warnings, precautions and possible adverse effects.

Plasmafit™ Pro Acetabular Cup System

Surgical Technique

II. System Overview



The Plasmafit Pro Acetabular Cup System consists of a pressfit titanium acetabular cup and a highly crosslinked ultra-high molecular weight polyethylene (UHMWPE) vitamin E liner.

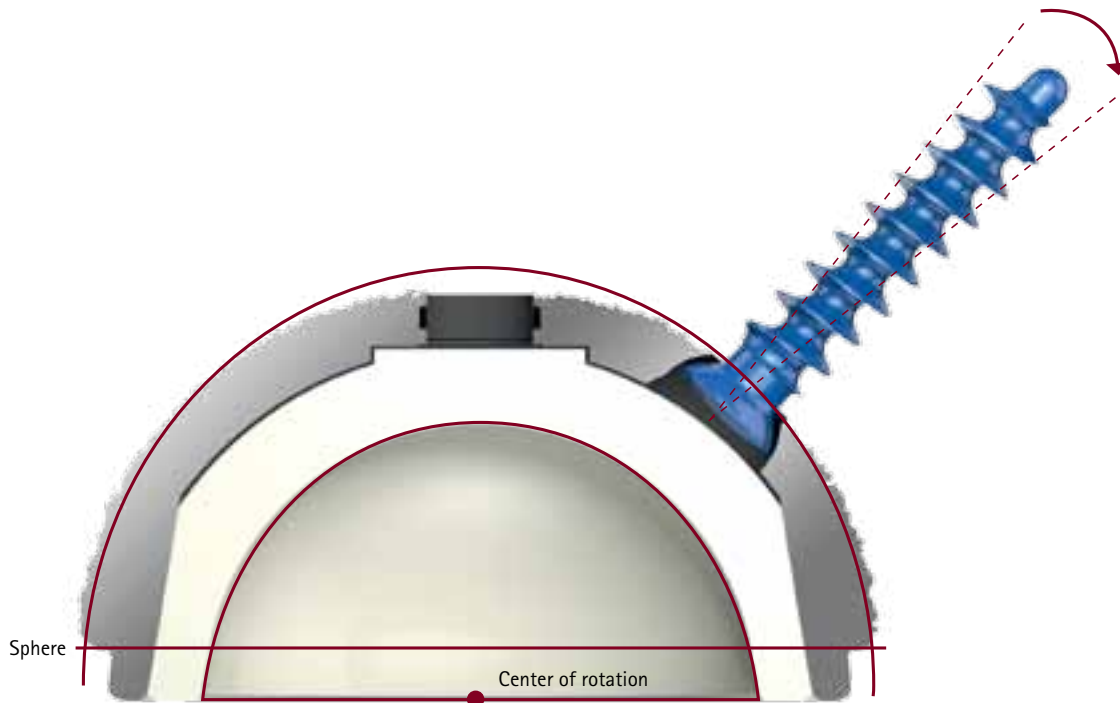
Plasmafit Pro Cup

The hemispherical titanium cup with a slightly flattened dome is coated with a titanium plasma spray on the outer surface, providing a high level of primary stability with its rough finish. The Plasmafit Pro cup is designed with an apex hole and three screw holes.

Plasmafit Pro Cancellous Screws

The Plasmafit Pro fixation screws have been designed with lower profile heads in order to optimize the cup's wall thickness.

The self-tapping, blue 6.5 mm screws are inserted with a 3.5 hex screw driver and allow a pivoting angle of $\pm 9^\circ$.



Vitelene Liner

Vitelene Liners are available in three designs: symmetrical, asymmetrical or posterior wall; each designed with a taper-fit to the interior surface of the Plasmafit Pro cups. The rough inner surface of the cup enhances a firm fixation

of the liner by reducing relative movement; therefore, preventing the formation of wear particles on the back side of the liner.

III. Surgical Technique



Fig. 1

1. Acetabular preparation

- Preoperative planning and x-ray templates may assist in determining the appropriate size and position of the acetabular component, Plasmfit Pro cup implants.
- Adequate acetabular exposure and removal of cartilage and osteophytes are required for proper preparation of the acetabulum.
- Using the spherical reamers, sequentially ream all articular cartilage, down to the subchondral bone, until bleeding occurs. (Fig. 1)
- To ensure a proper press-fit, ream to the size of the cup component that is to be implanted. This will provide a 1.6 mm press-fit.

For non-dysplastic cases, care must be taken not to medialize the center of rotation of the joint unnecessarily. The rim of the acetabulum should be prepared for a sufficient large bony fixation surface.

In cases of dysplastic changes, a cup position in the region of the primary socket is recommended, as far as a shortening of the leg can be compensated. The caudal edge of the shell should be at the level of the tear drop figure. If necessary, a cranial bone graft, to provide sufficient cranial roofing, is positioned before the socket base is prepared.



Fig. 2

Note:

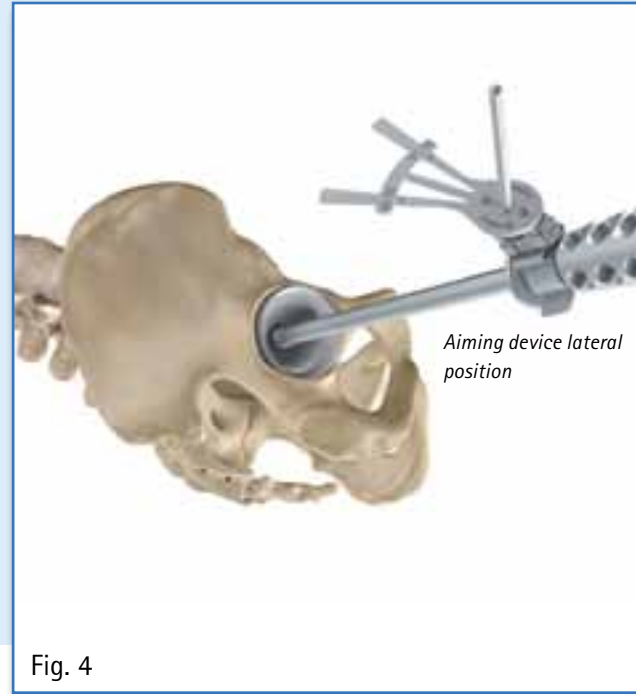
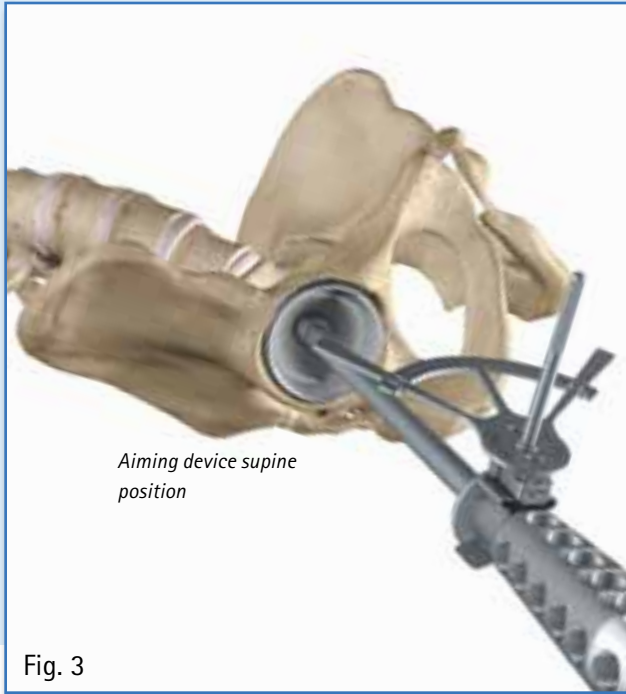
- Reamers should be driven by a low-speed motor hand-piece.
- Reaming should begin with a smaller size and be gradually increased by 1-2 mm.
- There is a 1 mm difference between the reamer and trial size.

2. Trial cup insertion

- After preparation of the acetabulum, a trial cup can be inserted to confirm the cup size and position. (Fig. 2)
- Attach the desired trial cup to either insertion instrument: straight or curved for less invasive surgical approaches.
- A stable fit of this trial cup is achieved when the pelvis of the patient can be moved slightly by gently moving the cup impactor. The trial implant can be easily levered out from the in vivo trial position by moving beyond this angle.

Plasmafit™ Pro Acetabular Cup System

Surgical Technique



3. Acetabular cup insertion

- Remove the trial cup from the insertion instrument and attach the final cup component that is to be implanted onto the insertion instrument.
- For the positioning of the Plasmafit™ Pro cup implant, aiming devices are available for either the supine or lateral patient position. Attach the desired aiming device onto the insertion instrument. (Fig's 3 & 4)
- Insert the insertion instrument into the acetabulum. Firmly tap at the end of the device with a mallet until the cup is properly seated.

Note: The aiming/insertion instrument is also suitable for assessing and adjusting the proper cup position inside the acetabulum.



Fig. 5

4. Additional screw fixation

- Plasmafit Pro cup should be rotated 180° prior to implantation, placing the three screw holes in the non load-bearing caudal region, if they are not needed cranially.
- However, the intra-operative primary stability of the Plasmafit Pro cup can be optionally used with screws. The cup should be rotated prior to implantation, placing the three screw holes in the cranial region. Using the 3.2 mm drill bit and drill guide, carefully drill through the acetabulum in the desired location. Measure for the appropriate screw length and insert the self-tapping 6.5 mm screw using the available screw holding forceps and cardan screw driver.

Note: To protect the medial blood vessels, the middle and lateral screw positions can be used, while the medial may be left open.

Note: Fully seat the screw heads below the inner surface of the cup, to ensure proper liner seating in the cup.



Fig. 6

5. Trial liner insertion and final liner insertion

- After completing the surgical steps of the acetabular component, a trial liner can be inserted to access the position of the final implant.
- Position the trial liner in the desired orientation.
- Upon obtaining a satisfactory final trial joint reduction and after the stem is implanted, the final liner can be inserted using an impactor with a plastic head.

Note: Liners with posterior wall (hooded) increase dislocation stability (e.g. towards posterior for implantations using the posterior surgical approach). The asymmetrical liners correct the cup position by 10 degrees.

Plasmafit™ Pro Acetabular Cup System

Surgical Technique

IV. Implant Overview

Cup implants

Cup size		46	48	50	52	54	56	58	60	62	64	66	68
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Liner size

	D	E	F	G	H	I	J	J	J	K	K	K
--	---	---	---	---	---	---	---	---	---	---	---	---

Plasmafit™ Pro	ISOTAN _F	NV846T	NV848T	NV850T	NV852T	NV854T	NV856T	NV858T	NV860T	NV862T	NV864T	NV866T	NV868T
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symmetrical Vitelene™



Ø 28 mm	NV190E	NV191E	-	-	-	-	-	-	-	-	-	-	-
Ø 32 mm	-	NV201E	NV202E	NV203E	NV204E	NV205E	-	-	NV206E	-	-	-	-
Ø 36 mm	-	-	-	NV213E	NV214E	NV215E	-	-	NV216E	-	NV217E	-	-
Ø 40 mm	-	-	-	-	-	NV225E	-	-	NV226E	-	NV227E	-	-

posterior wall Vitelene™



Ø 28 mm	NV290E	NV291E	-	-	-	-	-	-	-	-	-	-	-
Ø 32 mm	-	NV301E	NV302E	NV303E	NV304E	NV305E	-	-	NV306E	-	NV307E	-	-
Ø 36 mm	-	-	-	NV313E	NV314E	NV315E	-	-	NV316E	-	NV317E	-	-

asymmetrical Vitelene™



Ø 28 mm	NV390E	NV391E	-	-	-	-	-	-	-	-	-	-	-
Ø 32 mm	-	NV401E	NV402E	NV403E	NV404E	NV405E	-	-	NV406E	-	NV407E	-	-

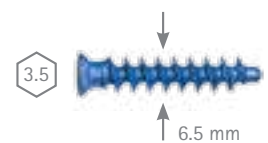


Plasmafit Pro

Plasmafit – Cancellous Screws

Length	
16 mm	NV010T
20 mm	NV011T
24 mm	NV012T
28 mm	NV013T
32 mm	NV014T
36 mm	NV015T
40 mm	NV016T
44 mm	NV017T
48 mm	NV018T
52 mm	NV019T
56 mm	NV020T
60 mm	NV021T
64 mm	NV022T
68 mm	NV023T

ISOTAN_F



Implant Materials:

Cup coating	Porous titanium plasma spray
ISOTAN _F	Titanium forged alloy (Ti6Al4V / ISO 5832-3)
UHMWPE	Ultra high molecular weight polyethylene (ISO 5834-2)
Vitelene™	UHMWPE-XE vitamin E stabilized highly crosslinked polyethylene

V. Instrument Overview



Tray 1: Basic Instrumentation

Consisting of:

Tray with storage and space for one small and one half module tray 489 x 253 x 106 mm	NT401R
Graphic template for NT400	TF072
Screw driver 4.5 hex	NT412R
Polyamid head Ø 28 mm	FS979
Polyamid head Ø 32 mm	FS980
Polyamid head Ø 36 mm	FS983
Polyamid head Ø 40 mm	FS988
Insertion instrument length 442 mm	NT410R
Insertion instrument curved length 442 mm	NT411R
Rotation and extraction plate	NT416R
Aiming device supine position	NT417R
Aiming device lateral position	NT418R
Caliper measures in diameter 100 mm	AA847R
Small empty tray to click into basic set 428 x 59 x 30 mm	NT397R



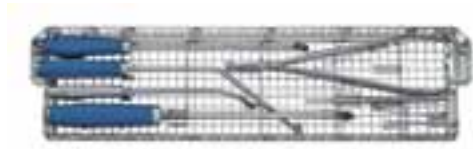
Tray 2: Trial Cup Module

Consisting of:

Half module tray with supports 465 x 118 x 45 mm	NT437R
Trial cup Ø 46 D	NT446R
Trial cup Ø 48 E	NT448R
Trial cup Ø 50 F	NT450R
Trial cup Ø 52 G	NT452R
Trial cup Ø 54 H	NT454R
Trial cup Ø 56 I	NT456R
Trial cup Ø 58 J	NT458R
Trial cup Ø 60 J	NT460R
Trial cup Ø 62 J	NT462R
Trial cup Ø 64 K	NT464R
Trial cup Ø 66 K	NT466R
Trial cup Ø 68 K	NT468R

Plasmafit™ Pro Acetabular Cup System

Surgical Technique



Tray 3: Screw Fixation Module

Consisting of:

Half module tray with supports 465 x 118 x 45 mm	NT403R
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Flexible drilling shaft	NT419R
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Drill bit Ø 3.2 mm, length 32 mm	NT424R
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Cardan screw driver 3.5 hex	NT428R
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Depth gauge	NT427R
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Drill guide straight Ø 3.2 mm	NT421R
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Drill guide curved Ø 3.2 mm	NT423R
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Screw holding forceps straight	NT432R
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Screw holding forceps curved	NT433R
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Tray 4: Trial Liner Module

Consisting of:

Half module tray for maximum
16 trial liners
465 x 118 x 45 mm

NT405R

Forceps for trial liners

NT430R

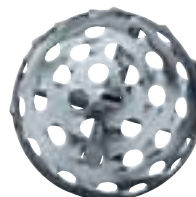
Liner size	D	E	F	G	H	I	J	K
Ø in mm								
symmetrical	28	NT490	NT491	-	-	-	-	-
	32	-	NT501	NT502	NT503	NT504	NT505	NT506
	36	-	-	-	NT513	NT514	NT515	NT516
	40	-	-	-	-	-	NT525	NT526
							NT517	NT527

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Surgical Technique



Tray 5 - Acetabular small reamers



With supports for:

Tray with supports for acetabular reamers

NF933R

Acetabular reamer heads

Item No.	Description	Item No.	Description
Dia. 40 mm	NF940R	Dia. 55 mm	NF955R
Dia. 41 mm	NF941R	Dia. 56 mm	NF956R
Dia. 42 mm	NF942R	Dia. 57 mm	NF957R
Dia. 43 mm	NF943R	Dia. 58 mm	NF958R
Dia. 44 mm	NF944R	Dia. 59 mm	NF959R
Dia. 45 mm	NF945R	Dia. 60 mm	NF960R
Dia. 46 mm	NF946R	Dia. 61 mm	NF961R
Dia. 47 mm	NF947R	Dia. 62 mm	NF962R
Dia. 48 mm	NF948R	Dia. 63 mm	NF963R
Dia. 49 mm	NF949R	Dia. 64 mm	NF964R
Dia. 50 mm	NF950R	Dia. 65 mm	NF965R
Dia. 51 mm	NF951R	Dia. 66 mm	NF966R
Dia. 52 mm	NF952R	Dia. 67 mm	NF967R
Dia. 53 mm	NF953R	Dia. 68 mm	NF968R
Dia. 54 mm	NF954R		



Tray 6 – Acetabular large reamers

Tray with supports for acetabular reamers Ø 60-68, one straight reamer shank one curved reamer shank and protection sleeve
465 x 118 x 45 mm

OrthoPilot® sleeve	FS939
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OrthoPilot® curved reamer shank ZIMMER	FS935R
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OrthoPilot® reamer shank ZIMMER	FS959R
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Notes

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DOC1103 1M 6/13