B BRAUN
SHARING EXPERTISE

AESCULAP® Plasmafit® Dual Mobility

Dual Mobility Articulation

AESCULAP® Plasmafit® Dual Mobility

Dual Mobility Modular Acetabular Liners

Dual Mobility in Hip Endoprosthetics

Larger head diameters, improved surgical techniques and the use of improved materials contributed to a reduction of intraprosthetic joint dislocations paired with a higher joint stability (1, 2).
An additional level for a treatment option for the acetabulum, offers the use of modular Dual Mobility liners that support postoperative joint stability and allow a high range of motion.

Dual Mobility liners can be used both in primary and revision surgeries. Especially under the aspect of a worldwide aging population a reduction of complications, e. g. for patients with a high risk of dislocation, is beneficial (2).

The basic dual mobility concept was invented already in 1976 by Prof. G. Bousquet with the aim of preventing chronic dislocations. The functionality of Plasmafit® Dual Mobility is based on this concept. A standard prosthesis head is pressed into a Dual Mobility polyethylene head of a large diameter. This head moves freely within the thin metal liner. The secondary articulation surface is provided by the Dual Mobility liner, allowing the Dual Mobility head to move freely on the highly polished inner surface of the metal liner.

(1) Cuthbert R, Wong J, Mitchell P, Jaiswal PK; Dual mobility in primary total hip arthroplasty: current concepts; EFORT Open Rev., Nov 2019, doi: 10.1302/2058-5241.4.180089.

(2) Li WT, Kozick Z, Sherman M, Restrepo C, Smith EB, Courtney PM; Dual Mobility Bearing Articulations Result in Lower Rates of Dislocation After Revision Total Hip Arthroplasty; J Am Acad Orthop Surg., Dez 2019. doi: 10.5435/JAAOS-D-19-00532.

Content

AESCULAP® Plasmafit® Dual Mobility

1 | Concept

Plasmafit® Dual Mobility

The Plasmafit® cup system stands for an acetabular treatment option within the cup family of AESCULAP®. Different requirements for patient specific solutions are combined in one system and complement each other by the use of the same instruments, design parameters and surgical procedure.

The Plasmafit® Dual Mobility concept adresses a high stability preventing hip joint dislocations.

Plasmafit® Dual Mobility liners can be combined with all cup options of the Plasmafit® Plus and Plasmafit® Revision cup implants. Dual Mobility combination is possible starting with cup size ø 46 mm.

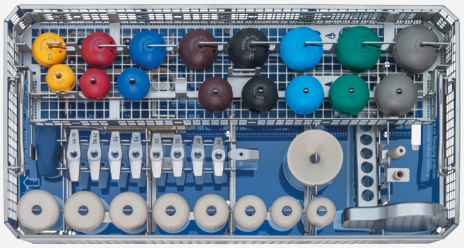
In case of revision with a stable and firmly seated Plasmafit® Plus or Revison cup, the surgery can be performed with the Plasmafit® Dual Mobility articulation without revising the cup.

Plasmafit® instruments offer one platform solution for the entire Plasmafit® system by adding specific Dual Mobility instruments. The instrument package and the continuation of the family concept allow intraoperative flexibility in the choice of bearing options. Both, Dual Mobility trial liners or standard trial liners can be selected for the combination with the acetabular cup.

Dual Mobility Liner

Vitelene® Dual Mobility Head

Plasmafit® Dual Mobility Set



One Family.
One Concept.

Plasmafit® Dual Mobility

Dual Mobility articulation in primary and revision surgeries for Plasmafit® Plus and Plasmafit® Revision

- ✓ Vitelene® highly crosslinked Vitamin E Dual Mobility head
- ✓ Metal on Metal contact avoidance by ceramic multilayer coating on the outer side of the Dual Mobility liner
- ✓ Dual Mobility treatment as of cup size 46 mm
- ✓ Intraoperative flexibility in the choice of bearing options: Dual Mobility liner or Standard liner
- ✓ Free 360° positioning of Dual Mobility liner in the
- ✓ Prosthesis heads ø 22.2 mm or ø 28 mm
- ✓ Instrument concept of Plasmafit® Family
- ✓ Complementing the proven Plasmafit® Family

AESCULAP® Plasmafit® Dual Mobility

2 | Components & Materials

Dual Mobility Liner

- ✓ Ceramic multilayer coating for an increased corrosion resistance (3)
- ✓ Good gliding properties and reduced wear with Vitelene® Dual Mobility head (4)
- ✓ Dual Mobility and screw fixation (5)

The Dual Mobility liner is inserted into the acetabular cup implant and fixed via a conical fixation.

On the outside the liner is coated with a ceramic multilayer coating. It is a seven layer coating concept that specifically supports the corrosion resistance of the outer surface of the Dual Mobility liner (3).

The inner side is highly polished and serves as the articulation surface for the Dual Mobility head made of Vitelene® highly crosslinked polyethylene with vitamin E and offers good gliding properties as well as abrasion reduction for the Vitelene® Dual Mobility head (4).

Dual Mobility liner can be used with Plasmafit® Plus or Plasmafit® Revision cup implants, even with fixation screws (5).

Modular Dual Mobility Liner

Vitelene® Dual Mobility Head

- ✓ Highly crosslinked PE with vitamin E stabilization
- ✓ Reduced wear (4)
- ✓ Oxidation reduction (6)

Vitelene® is a highly crosslinked polyethylene stabilized with vitamin E. Vitamin E provides longterm oxidation protection by binding free radicals through the release of H atoms and thus provides longterm protection against oxidation. Polyethylene powder GUR1020 is mixed with vitamin E (0.1 %-alpha-Tocopherol) and pressed into sheets. Afterwards a total dose of 80 kGy electron beam radiation is applied to cross link the blank product.

The implants manufactured with CNC technology are sterilized with ethylene oxide and packed in a nitrogen atmosphere.

The Dual Mobility heads are compatible with prosthesis heads with diameter 22.2 mm (connection size to the cup D to F) and with diameter 28 mm (connection size to the cup G to K).

Further informations on Vitelene® in the scientific brochure 044302.

(3) Aesculap AG; Test report V2035, Fretting Corrosion Behaviour of the Dual Mobility Inserts, August 2019. The Dual Mobility Liners have been tested on fretting corrosion behaviour compared to a competitor product and showed a significantly lower corrosion behaviour.

(4) Aesculap AG; Test report T455, Determination of the Wear Behaviour of the Dual Mobility System; July 2019. The average wear rates of Vitelene® Dual Mobility Liners have been tested and the results are well below the threshold value that reported to literature may lead to osteolysis.

(5) Aesculap AG, Rationale, Compatibility of Plasmafit® Cups with Fixation Screws and the Dual Mobility Inserts, July 2019. The Dual Mobility Liners have no risk of possible collision with the fixation screws. The Dual Mobility Liners have a smaller backside geomerty than standard liners of Plasmafit® cups.

(6) Grupp T et al. Biotribology of a vitamin E-stabilized polyethylene for hip arthroplasty – Influence of artificial ageing and third-body particles on wear. Acta Biomaterialia. 2014 Jul;10(7):3068-78. Epub 2014 Mar 12.

AESCULAP® Plasmafit® Dual Mobility

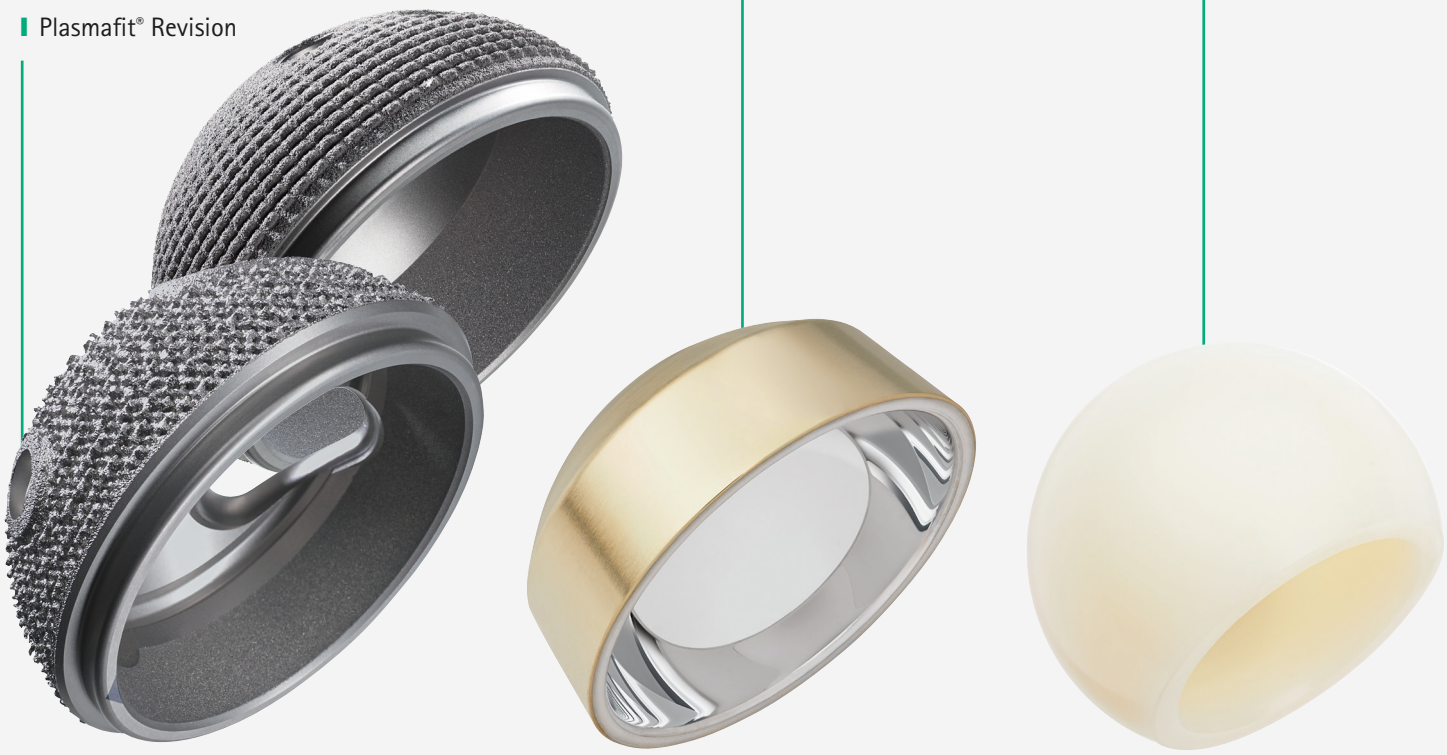
3 | Treatment Concept

Plasmafit® Dual Mobility Treatment

Cup implant
- Plasmafit® Plus or
- Plasmafit® Revision

Dual Mobility liner

Dual Mobility head



Modular Solution

AESCULAP® Prosthesis heads*

- Biolox® delta Ceramic head or
- Isocer® Ceramic head or
- CoCr Prosthesis head or
- Biolox® Option Ceramic Revision head

Or:

- Dual Mobility CoCr Prosthesis head

* Depending on the approved combination, please refer to p. 18 and p. 19

AESCULAP® Plasmafit® Dual Mobility

4 | Cup Components

Plasmafit® Plus

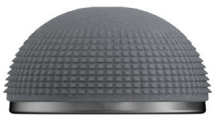
- ✓ Universal cup implant line with screwing option
- ✓ Thick cup design offers the use of ceramic, polyethylene or Dual Mobility liners
- ✓ Cup option with no, 3 or 7 screw holes
- ✓ Proven Plasmapore® surface
- ✓ Closing plug for cup line without screw holes
- ✓ Dual Mobility starting with cup size 46 mm

Plasmafit® Plus is intended for the combined treatment with Biolox® delta ceramic, Vitelene® or conventional polyethylene as well as Plasmafit® Dual Mobility articulating options. The cup's wall thickness allows additional screw holes for an optional use of cancellous fixation screws.

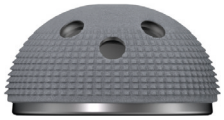
Plasmafit® Plus can be combined with Dual Mobility components starting with cup size 46 mm with a ø 22.2 mm prosthesis head, and as of cup size 52 mm with a ø 28 mm prosthesis head.

The anchoring of the Plasmafit® Dual Mobility liner is realized by a large conical locking mechanism.

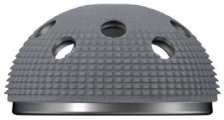
Plasmafit® Plus
no screw holes



Plasmafit® Plus 3
with 3 screw holes



Plasmafit® Plus 7
5 screw holes cranially,
2 screw holes caudally



Plasmafit® Revision

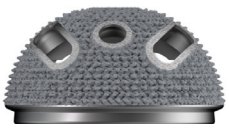
- ✓ Implant line for primary and revision treament
- ✓ Cup design with oblong screw hole options
- ✓ 3 screw holes cranially, 2 caudally
- ✓ Additive titanium surface
- ✓ Polyethylene or Dual Mobility liner
- ✓ Dual Mobility starting with cup size 46 mm

The design of the Plasmafit® Revision internal geometry allows an intraoperative selection of modular liners for the treatment with Vitelene® or conventional polyethylene as well as Plasmafit® Dual Mobility articulation options. To achieve good stability in larger acetabular defects, the design has a total of five holes for screw anchoring.

Plasmafit® Revision can be combined with Dual Mobility components starting with cup size 46 mm with a ø 22.2 mm prosthesis head, and as of cup size 52 mm with a ø 28 mm prosthesis head.

The anchoring of the Plasmafit® Dual Mobility liner is realized by a large area conical locking mechanism.

Plasmafit® Revision
3 screw holes cranially,
2 screw holes caudally



AESCULAP® Plasmafit® Dual Mobility

5 | Surgical Technique

Preparation and Implantation of the Cup Implant

Preoperative planning in hip surgery is recommended to understand the patient specific anatomy as well as to determine the cup size, implant components and desired position for anchoring the acetabular cup. The bone should be prepared accordingly.

The cup implant Plasmafit® Plus or Plasmafit® Revision is implanted according to the corresponding surgical technique and instructions for use.

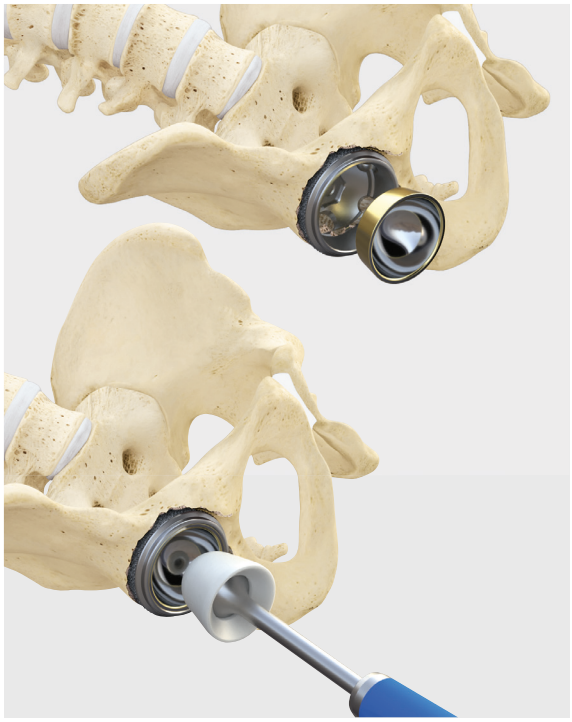
Optional: Insertion of Trial Liner

A trial liner is manually inserted into the cup implant to determine the Dual Mobility cup insert or for trial positioning.

The trial liners can be removed by the help of the removal forceps.

Implantation of Dual Mobility Liner

The Dual Mobility liner is inserted in the cup implant. The proper seating of the liner is assessed with a fingertip check. The liner is fixed with the insertion instrument. The plastic attachment is placed centrally in the Dual Mobility insert. The conical insert is fixed in the cup implant with an impulse.
Finally, the correct seating should be checked once again with the fingertip.



Implantation of the Femoral Stem

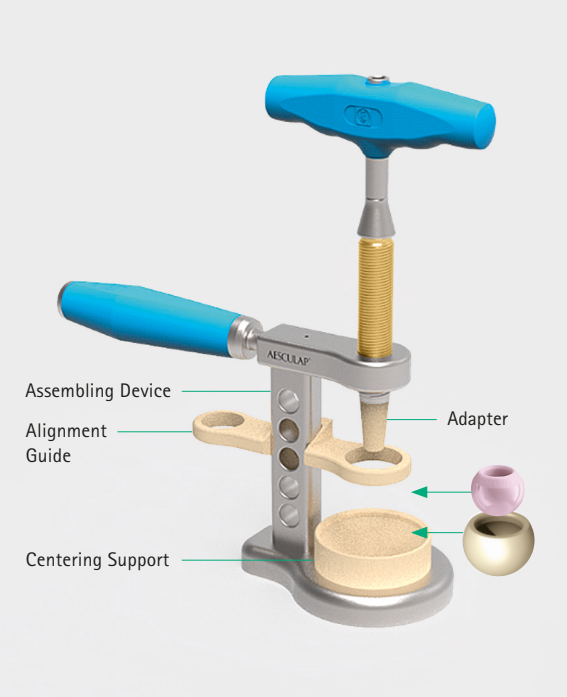
The femoral stem is implanted according to the corresponding surgical technique and instructions for use. The combination possibilities need to be taken into account (please refer to p. 19 and 20 for more details).

Optional: Reduction with Trial Instruments

The trial Dual Mobility head can be placed in the implanted Dual Mobility liner. This is connected to the trial prosthesis head, which is placed on the inserted stem for joint reduction. This determines the neck length of the prosthesis head and checks the joint mobility.

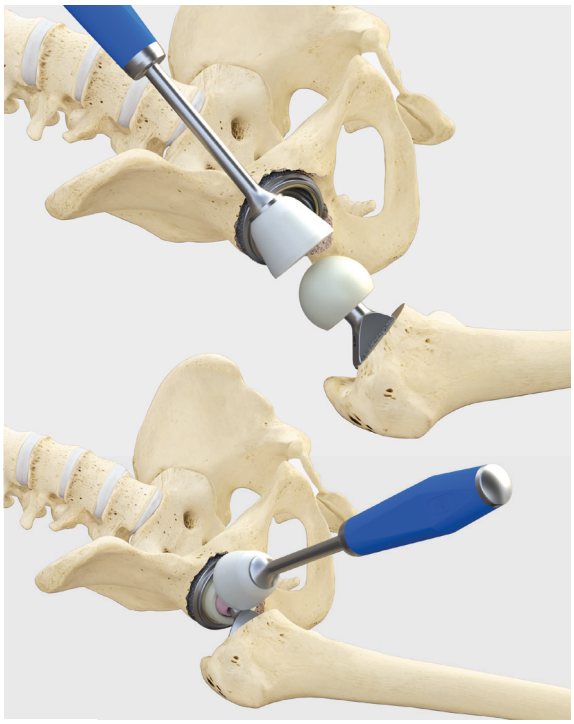
AESCULAP® Plasmafit® Dual Mobility

5 | Surgical Technique



Assembling of Dual Mobility Head and Prosthesis Head

For assembling, the Vitelene® head is placed in the centering support with the opening facing upwards. The alignment guide is a doublesided instrument that is placed on the edge of the Vitelene® head in order to prevent any tilting of the liner during the assembling process. The small opening is for prosthesis heads ø 22.2 mm and the large opening for prosthesis heads ø 28 mm. The alignment guide is freely adjustable vertically along the assembling device. The prosthesis head is then positioned in the alignment guide on the Vitelene® head. Depending on the taper of the stem/prosthesis head, two different adapters are available: a 12/14 or an 8/10 adapter. The corresponding adapter is attached to the assembling instrument.
By turning the upper handle, the adapter is moved downwards and thus inserted into the prosthesis head. By turning it further, the prosthesis head is inserted into the Vitelene® Dual Mobility head. The final assembly can be determined by means of a haptic and auditive feedback.



Insertion and Reduction of Dual Mobility Head

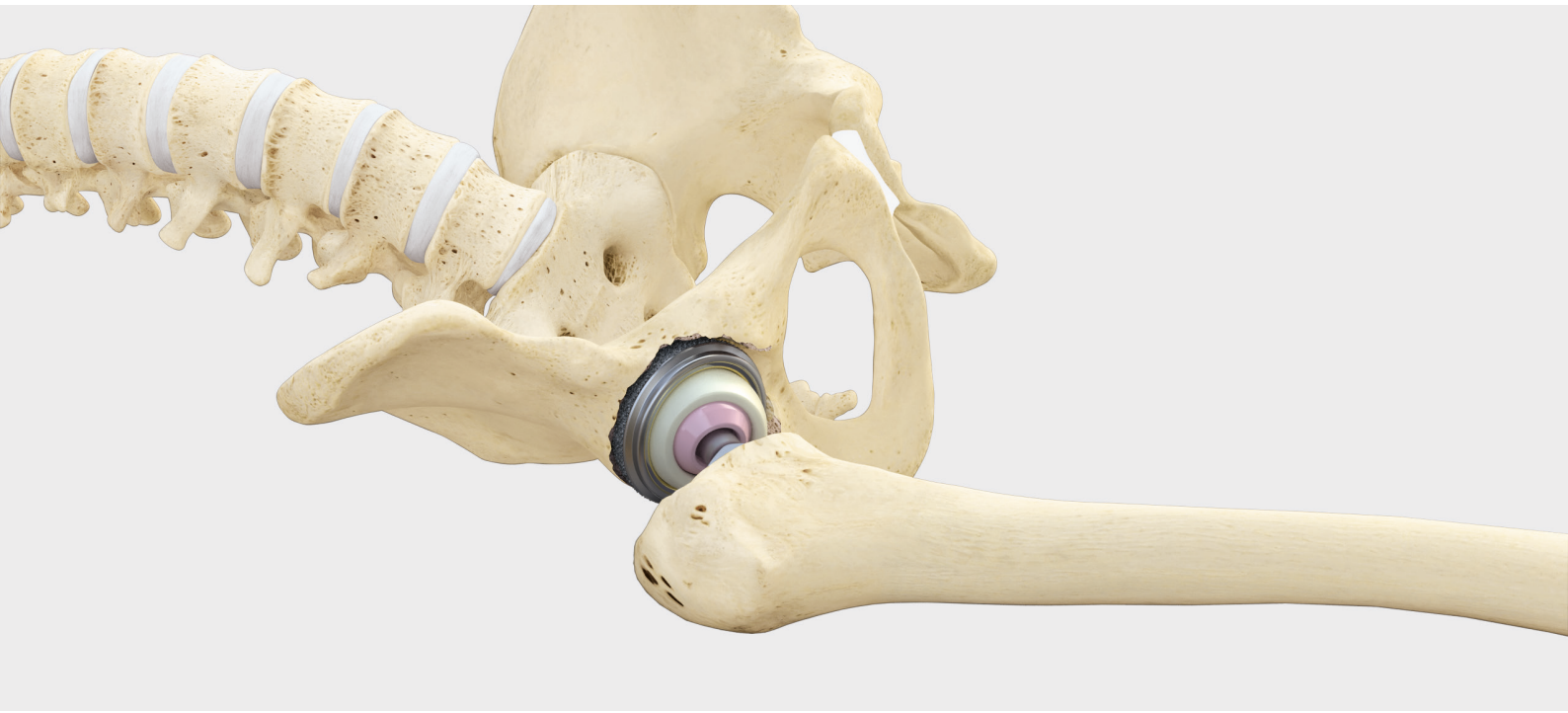
NOTE

After the assembling process, check if the prosthesis head can move freely in the Vitelene® Dual Mobility head. It can then be inserted.

The assembled Dual Mobility head is placed on the taper of the femoral stem component. The insertion instrument is placed on the Dual Mobility head and thus the ex situ assembled implant components are fixed on the taper.
The final step is a final joint reduction and a further check for joint stability, leg length and functionality.

NOTE

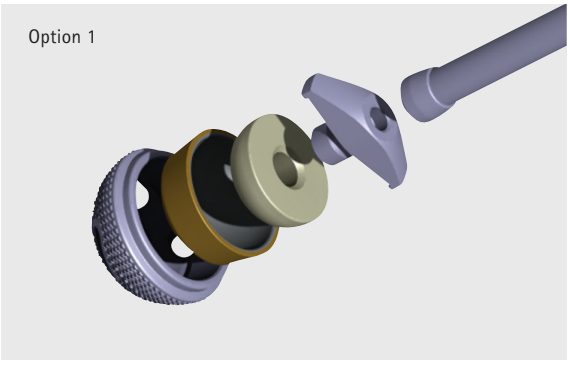
The two assembled components, prosthesis head and Vitelene® Dual Mobility head, cannot be separated into two parts and reused after being combined.



Dual Mobility Liner Revision

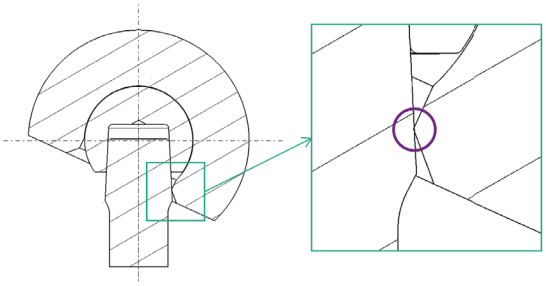
The implanted Dual Mobility liners can be removed by the help of special attachments that can be attached to the cup insertion instrument. It is important to place the instruments precisely on the rim of the metal shell. The separation of the liner from the cup is done with several impulses to dissolve the conical fixation. The liner can then be removed.

Please refer to the corresponding instructions for use.

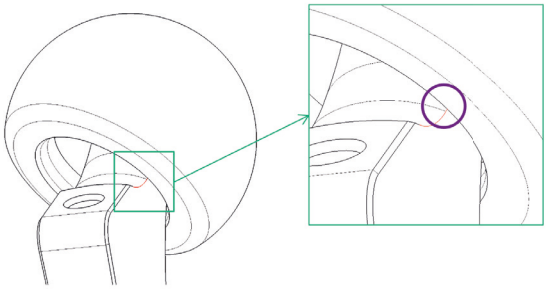


AESCULAP® Plasmafit® Dual Mobility

6 | Combinations



Contact with rough surface like taper to be avoided



Contact with sharp edges to be avoided

Plasmafit® Dual Mobility Combinations

Several aspects need to be considered for a Dual Mobility articulation with AESCULAP® hip stems, in order to match latest biomechanical requirements as well as addressing a comprehensive solution for the AESCULAP® hip stem portfolio.

Reduction of wear and contact with the Dual Mobility head

Biomechanics in correspondence with Dual Mobility need to consider the surface roughness of the stem's neck knowing that a polished neck leads to better impingement parameters. (7)

A contact in between the Dual Mobility head and sharp edges of the prosthesis stem needs to be avoided to reduce wear and material loss in the mid- to long-term perspective. (7)

Evaluating the mentioned criteria for AESCULAP® stems in combination with Plasmafit® Dual Mobility leads to restrictions in assorted combinations with standard prosthesis heads. The limitations are necessary to avoid a regular impingement between Dual Mobility head and stem's neck, inherent to the Dual Mobility articulation principle.

Details about approved combinations as well as restrictions are listed in the table as follows. Even for limited combinations AESCULAP® offers a solution for a dual mobility articulation with the special Dual Mobility prosthesis head.

(7) Di Laura A, et. al. Retrieval evidence of impingement at the third articulation in contemporary dual mobility cups for total hip arthroplasty. Int Orthop. 2017.

Backward Compability for all AESCULAP® Stems

AESCULAP® provides hip endoprostheses for decades. Within this time-frame modifications in the taper geometries and shape took place in various stem lines to address continuously latest standard.

The modern AESCULAP® taper generation herewith is already on the level to meet the biomechanical requirements for a dual mobility articulation as described above.

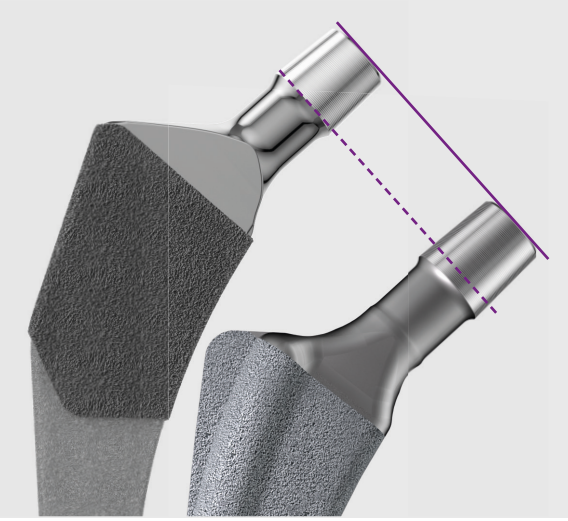
For the classic AESCULAP® taper generation, the extension to a Dual Mobility prosthesis head supports a suitable solution and supports a backward compatibility, if needed.

The special Dual Mobility CoCr prosthesis head is available bridging the, as critical defined, contact zones with a thin collar offering further combinations in the best possible way. Additionally, the collar is highly-polished to address surface criteria.

It is available for 12 / 14 taper with Ø 28 mm and for 8 / 10 taper in Ø 22.2 mm and Ø 28 mm.

NOTE

Please refer to p. 18 and check the combination overview table for a possible combination with Plasmafit® Dual Mobility as indicated in the corresponding Instructions for Use.



Modern Taper (shortend)	Classic Taper
CoreHip® TrendHip® Prevision® Update Prevision® Monobloc	All other AESCULAP® stems

Overview of AESCULAP® taper generations

Dual Mobility Prosthesis Head

AESCULAP® Plasmafit® Dual Mobility

6 | Combinations

Possible combinations of Dual Mobility system with AESCULAP® implants for 12/14 taper stems

Stem Type 12/14	ø 22.2 mm (cup diameter 46 - 50 mm)		ø 28 mm (cup diameter 52 - 70 / 72 mm)		
	M	L	S	M	L
CoreHip®	STD	✘	STD	STD	STD
TrendHip®					
Prevision® Update (polished neck)					
Prevision® Monobloc					
Prevision® Classic	✘	✘	STD	STD	✓
Trilliance®					
Excia® T (cementless)					
Excia® 12/14	✘	✘	✓	✓	✓
Excia® T (cemented)					
Bicontact® S/H (cemented)					
Centrament®					
SLA					
Metha® 135°/130°					
Bicontact® S/H (cementless)	✘	✘	✘	✓	✓
Bicontact® Revision / SD / SDC					
Metha® 120°					
TRJ®					

STD Standard head (Isocer®, Biolox® Delta, Biolox® Option, AESCULAP® CoCr head)

✓ Combination only possible with Dual Mobility prosthesis head

✘ No Dual Mobility combination possible

Possible combinations of Dual Mobility system with AESCULAP® implants for 8/10 taper stems

Stem Type 8/10	ø 22.2 mm			ø 28 mm		
	S	M	L	S	M	L
Bicontact® N/E/D	✓	✓	✓	✗	✓	✓
Excia® (cemented/cementless)	✓	✓	✓	✗	✓	✓
Trilliance®	✓	✓	✓	✗	✓	✓

✓ Combination only possible with Dual Mobility prosthesis head

✗ No Dual Mobility combination possible

AESCULAP® Plasmafit® Dual Mobility

7 | Implants

Plasmafit® Implants

Cup size		46	48	50	52	54	56
Liner size		D	E	F	G	H	I
Plasmafit® Plus	Ti6Al4V	NV146T	NV148T	NV150T	NV152T	NV154T	NV156T
Plasmafit® Plus 3	Ti6Al4V	NV246T	NV248T	NV250T	NV252T	NV254T	NV256T
Plasmafit® Plus 7	Ti6Al4V	NV346T	NV348T	NV350T	NV352T	NV354T	NV356T
Plasmafit® Revision	Structan®	NV946T	NV948T	NV950T	NV952T	NV954T	NV956T
Dual Mobility Liner		NV1010Z	NV1011Z	NV1012Z	NV1013Z	NV1014Z	NV1015Z
CoCr Ceramic multilayer coating made from chromium nitride-chromium-carbonitride-zirconium nitride							
Vitelene® Dual Mobility head	ø 22.2 mm	NV1030E	NV1031E	NV1032E	-	-	-
	ø 28 mm	-	-	-	NV1043E	NV1044E	NV1045E
Vitelene®							

Cup size		58	60	62	64	66	68	70	72
Liner size		J	J	J	K	K	K	K	K
Plasmafit® Plus	Ti6Al4V	NV158T	NV160T	NV162T	NV164T	NV166T	NV168T	NV170T	
Plasmafit® Plus 3	Ti6Al4V	NV258T	NV260T	NV262T	NV264T	NV266T	NV268T	NV270T	
Plasmafit® Plus 7	Ti6Al4V	NV358T	NV360T	NV362T	NV364T	NV366T	NV368T	NV370T	
Plasmafit® Revision	Structan®	NV958T	NV960T	NV962T	NV964T	NV966T	NV968T	NV970T	NV972T
Dual Mobility Liner		NV1016Z			NV1017Z				
CoCr Ceramic multilayer coating made from chromium nitride-chromium-carbonitride-zirconium nitride									
Vitelene® Dual Mobility head	ø 22.2 mm	-			-				
	ø 28 mm	NV1046E			NV1047E				
Vitelene®									

Ceramic – Prosthesis Heads

Biolox® delta - 12/14

Neck length	Art. no.		Art. no.	
	ø 22.2 mm	ø 28 mm	ø 22.2 mm	ø 28 mm
S	-	NK460D	-	NJ101D
M	-	NK461D	-	NJ102D
L	-	NK462D	-	NJ103D
	12/14		8/10	

Isocer® - 12/14

Neck length	Art. no.	
	ø 22.2 mm	ø 28 mm
S	-	NK324
M	-	NK325
L	-	NK326
	12/14	

Metal – Prosthesis Heads

CoCr - 12/14

Neck length	Art. no.		Art. no.	
	ø 22.2 mm	ø 28 mm	ø 22.2 mm	ø 28 mm
S	-	NK429K	NJ111K	NJ131K
M	NK330K	NK430K	NJ112K	NJ132K
L	NK331K	NK431K	NJ113K	NJ133K
	12/14		8/10	

Metal – Dual Mobility Prosthesis Heads

CoCr - 12/14

Neck length	Art. no.		Art. no.	
	ø 22.2 mm	ø 28 mm	ø 22.2 mm	ø 28 mm
S	-	NK1090K	NJ180K	NJ190K
M	-	NK1091K	NJ181K	NJ191K
L	-	NK1092K	NJ182K	NJ192K
	12/14		8/10	

AESCULAP® Plasmafit® Dual Mobility

7 | Implants

Ceramic – Prosthesis Heads, Biolox® Option

Neck length	Art. no.	
	ø 22.2 mm	ø 28 mm
S	-	NK435
M	-	NK436
L	-	NK437
	12/14	

Biolox® delta - 12/14
with sleeve Ti6Al4V

NOTE

Biolox® Option heads are delivered with a cone sleeve 12/14. For 8/10 tapers please order the Biolox® Option sleeves shown below.

Biolox® Option Sleeve for 8/10 taper

Neck length	Art. no.
S	NJ435T
M	NJ436T
L	NJ437T

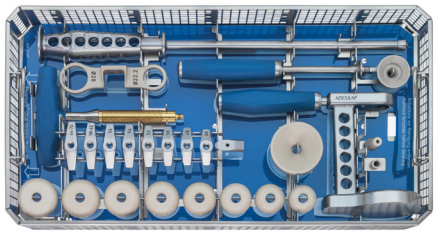
Ti6Al4V

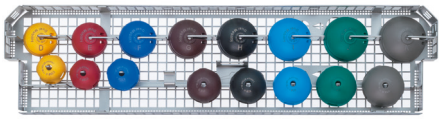
8/10

Implant Materials:

Biolox® delta	Aluminium oxide matrix ceramic (Al_2O_3/ZrO_2/ISO 6474-2)
Isocer®	Zirconia-toughened alumina ceramic (Al_2O_3/ZrO_2/ISO 6474-2)
CoCr	Cobalt-chromium forged alloy (CoCrMo/ISO 5832-12)
Ti6Al4V	Titanium forged alloy (Ti6Al4V/ISO 5832-3)
Plasmapore®	Pure titanium (Ti/ISO 5832-2)
Structan®	TI6Al4V ELI in accordance to ASTM F3001 and on the basis of ASTM F136
Vitelene®	UHMWPE-XE Vitamin E stabilized highly crosslinked polyethylene

Plasmafit® Dual Mobility Basic Set NT1500





Consisting of:	Art. no.
Tray with storage and space for one half module tray 489 x 253 x 106 mm	NT1501R
Lid	JH217R
Graphic template for NT1500	TF120
Impaction and reduction instrument	NT1528
Assembling device for Dual Mobility head	NT1520R
12/14 Adapter f. assembling device NT1520R	NT1522
Alignment guide f. assembling device NT1520R	NT1523
Centering support f. assembling device NT1520R	NT1524
Universal removal attachment	NT431R
Half module tray with supports 428 x 59 x 30 mm	NT1571R
Trial head D 22.2 mm	NT1530
Trial head E 22.2 mm	NT1531
Trial head F 22.2 mm	NT1532
Trial head G 28 mm	NT1543
Trial head H 28 mm	NT1544
Trial head I 28 mm	NT1545
Trial head J 28 mm	NT1546
Trial head K 28 mm	NT1547

	Please order separately:	Art. no.
	8/10 Adapter for assembling device NT1520R	NT1521
Trial instruments	Removal forceps for trial inserts	NT430R
	Trial liner D 33 mm	NT1510
	Trial liner E 35 mm	NT1511
	Trial liner F 37 mm	NT1512
	Trial liner G 39 mm	NT1513
	Trial liner H 41 mm	NT1514
	Trial liner I 43 mm	NT1515
	Trial liner J 45 mm	NT1516
	Trial liner K 47 mm	NT1517
Removal attachments	Bar for size 46 mm D	NT472R
	Bar for size 48 mm E	NT473R
	Bar for size 50 mm F	NT474R
	Bar for size 52 mm G	NT475R
	Bar for size 54 mm H	NT476R
	Bar for size 56 mm I	NT477R
	Bar for size 58-62 mm J	NT478R
	Bar for size 64-70 mm K	NT479R
	Removal attachment D	NT1572
	Removal attachment E	NT1573
	Removal attachment F	NT1574
	Removal attachment G	NT1575
	Removal attachment H	NT1576
	Removal attachment I	NT1577
	Removal attachment J	NT1578
	Removal attachment K	NT1579
	Insertion instrument, straight 442 mm	NT410R*
	Insertion instrument, straight 337 mm	NT414R*

* In the basic set NT1500 only one insertion instrument can be stored.

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