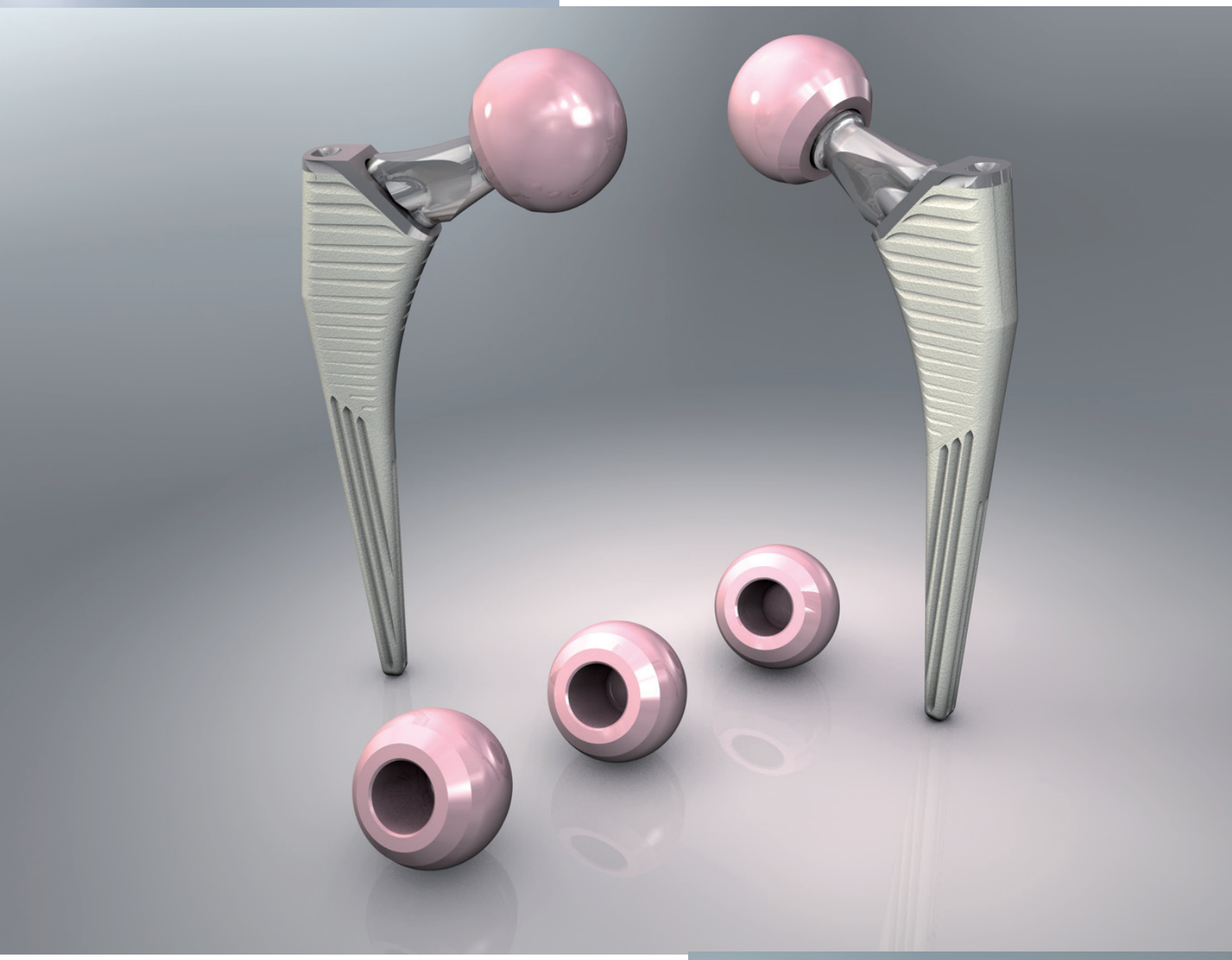
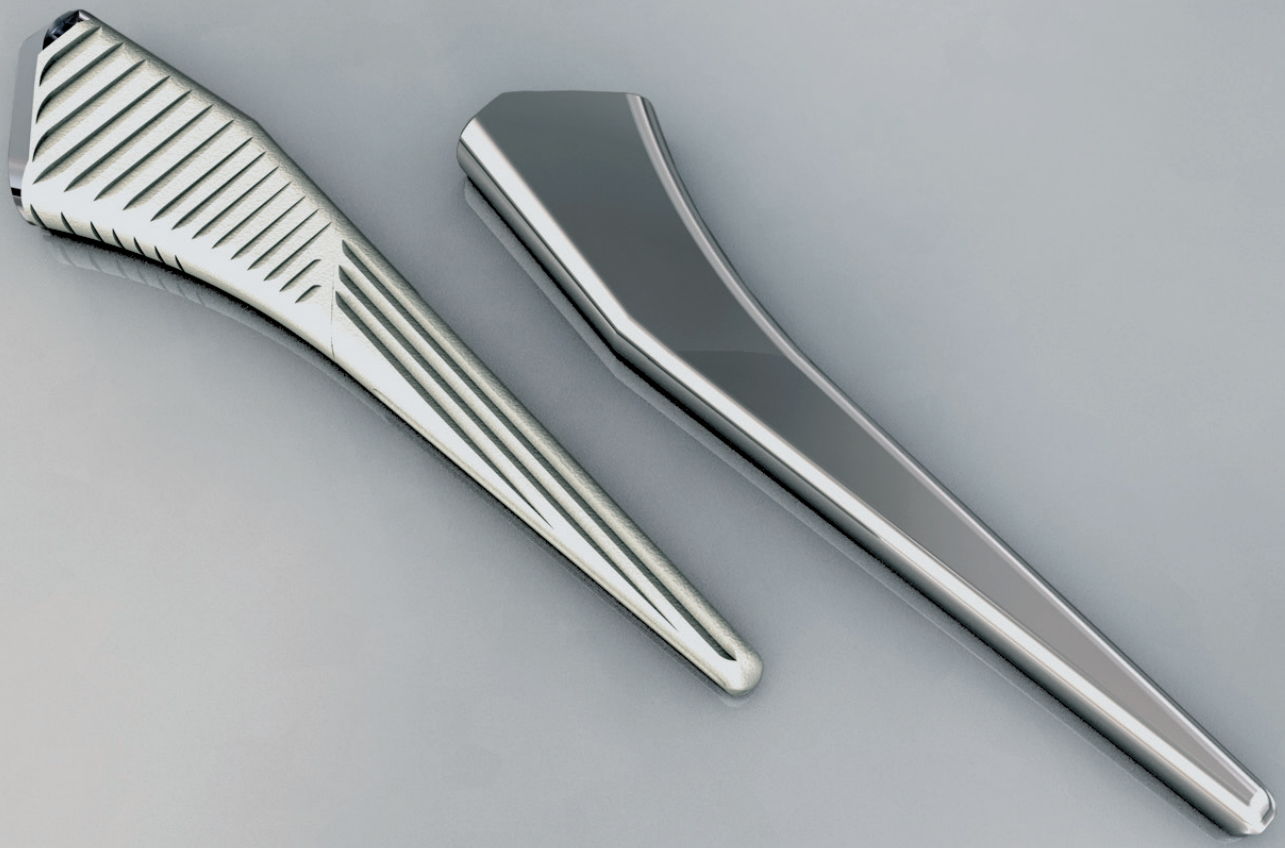
Hydra



ADLER® ORTHO

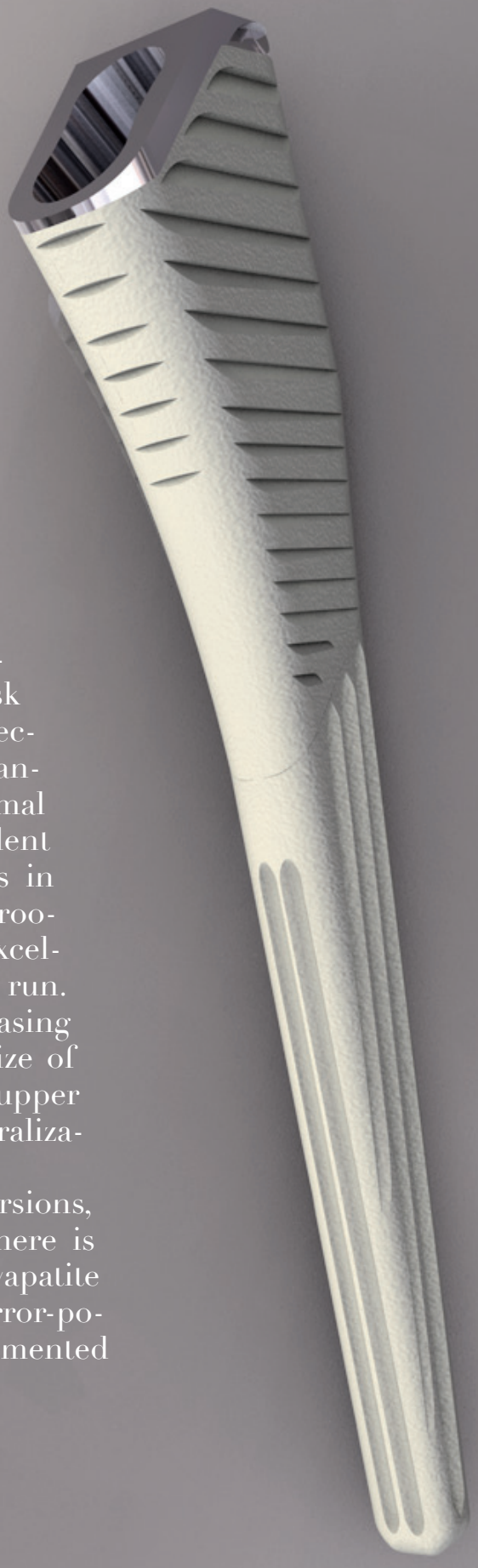
HYDRA



PRESENTATION

The HYDRA prosthesis system made of Titanium alloy (Ti6Al4V conforming to standards ISO5832-3) is designed with the specific intention of combining the features of a "press fit" stem entirely covered with hydroxyapatite (80 +/-- 20 microns) with the modularity offered by the MODULA SC system. The special progressive double-taper profile of the metaphyseal portion designed to avoid risk of sinking, the quadrangular cross-section meant for increasing the resistance to twisting and the accurate proximal filling of the femur guarantee excellent primary stability. Horizontal grooves in the metaphyseal region and vertical grooves in the distal region guarantee excellent mechanical fixation in the long run. A shiny collar with dimensions increasing progressively with increase in the size of the stem is placed in the proximal-upper part of the stem to help optimize lateralization of all sizes.

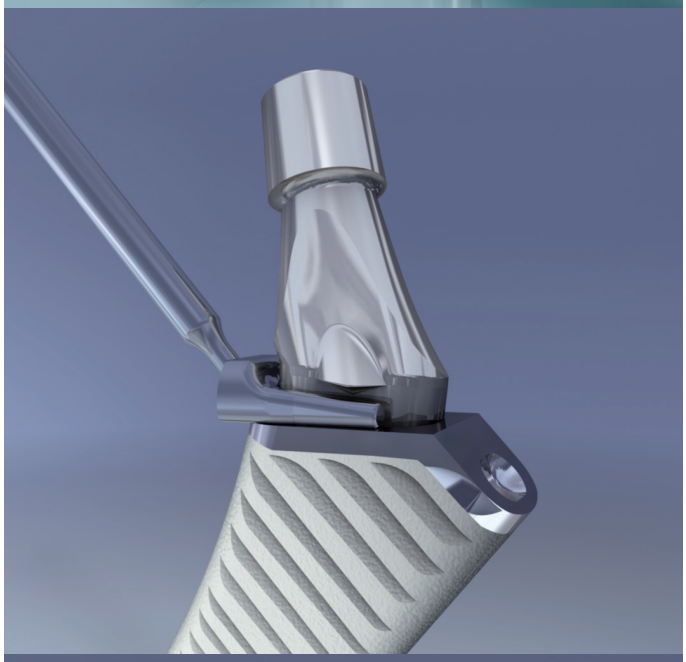
The Hydra stem is available in two versions, each consisting of 10 sizes sizes. There is one cementless range with hydroxyapatite coating and a range with smooth, mirror-polished surface to be used with the cemented technique.



MODULAR NECKS

One of the few conceptual evolutions of great importance in orthopaedic hip surgery in the last 20 years, the modularity of the extramedullary component (femoral neck) has been of undoubted value. In particular, the MODULA SC necks system, unlike other modular neck systems, makes it possible to adapt a standard implant to the various anatomo-physiological features of the patient without having to provide for an excessive number of sizes and, what is more important, without affecting the correct positioning and thereby the stability of the stem and cup in the long run.
The complete series of MODULA SC necks, all patented, consists of 15 sizes and makes it possible to optimize the reciprocal position of the stem and cup on the basis of the articular needs of the patient, by restoring the physiological off-set and length.
So what are the reasons that have induced us to continue with the search for innovative and improved solutions of Modula necks?
The life expectancy of human beings is certainly increasing while the average age of patients with a higher level of physical activity is decreasing.
An accurate study of data collected in prosthesis registers has shown a distinct increase in the number of overweight patients, in the last few years.
The wide spatial coverage of Modula SC necks can restore the operated patient the possibility of carrying out the same movements as those before the disease started.

Therefore, the patients are younger, live longer, are heavier and carry out more intense physical activity. All this requires new, high performance prosthetic systems capable of ensuring



greater freedom of movement and higher levels of mechanical resistance than in the past.

HYDRA

In the context of the program of ongoing improvement of our products, and in the light of what has been said above, it seemed indispensable for us to develop a new trial system which makes it possible to measure the stress in extreme conditions and indicate to us where and how to act to be able to design an instrument specific for this type of patients. We thus reached the idea of Modula "Super Charged" necks, designed for those who, because of their weight or the type of activity, or simply for greater freedom of movement, can bring the stress applied to the neck to levels much higher than the normally average levels known so far. The new Modula SC necks with their reinforcing fins, also useful as a system of removal of the neck from its seat in the stem, can amply pass the most demanding tests, more brilliantly than other solutions, as has be proved by laboratory tests.

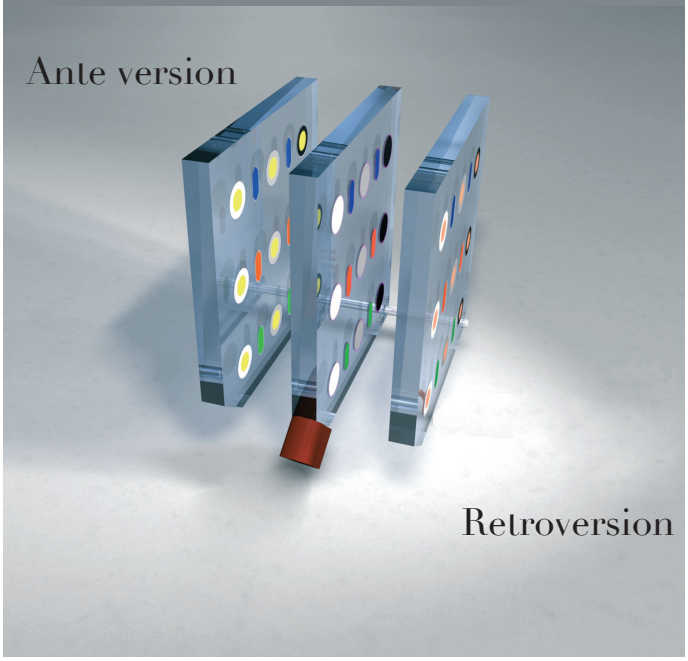
GEOMETRIC SOLUTION TO CLINICAL PROBLEMS

The matrix distribution in space allows uniform coverage, adjusting the three main parameters:

LENGTH OFFSET - VERSION

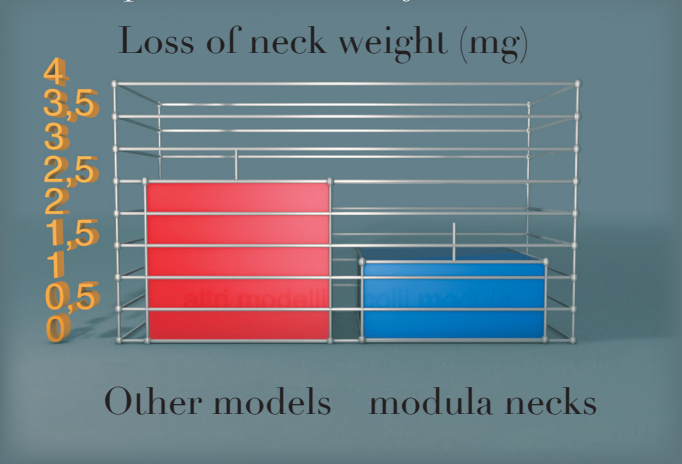
These can be selected independently of one another and sequentially, so that it is possible to make the modifications necessary during the various phases of the operation, from pre-operative planning to surgery.
For this reason it was necessary to abandon the policy of angular necks in the long neck and short neck version, on the varus/valgus plane as well as the ante/retroversion.
The MODULA SC necks are designed for such lengths and angles as to occupy a predefined position at a point on a three-dimensional matrix.
The guarantee of removability (separation of the neck from the stem) is of fundamental importance to be able to exploit all the features of the MODULA SC necks.
The removal proposed by us is patented, and the separation force is always applied in the direction of the coupling axis also on angular necks.
The MODULA SC necks solve various problems.

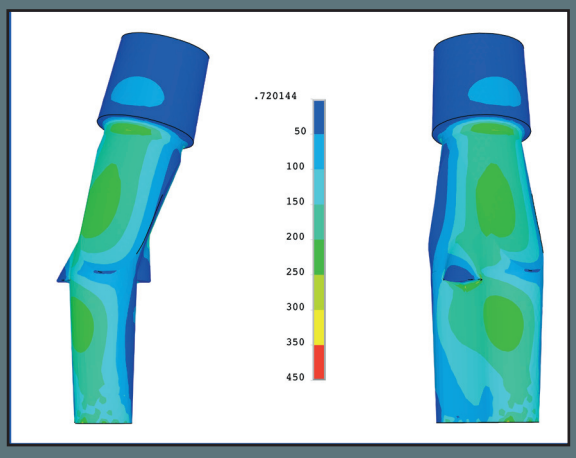
For example: Left hip



HYDRA
MECHANICAL SOLUTION TO RESISTANCE PROBLEMS

The hourglass shape with double elongated cone is designed to ensure contact between the surfaces of the cavity of the stem and that of the neck cone which are mainly subjected to mechanical stresses.
The coupling design has been developed and validated for the subsequent phases.
1) Numerous studies have made it possible to optimize the hourglass shape of the tapered fit. The shape and the positioning of the reinforcement fins and extraction of the neck are studied to avoid affecting the coupling solidity and to reduce the mechanical stresses when the implant is subjected to physiological loads.
2) Fatigue tests have shown that the most critical configuration can resist a cyclic load 200% greater than the limit value established by the international standard ISO 7206 8 applicable.
3) Fretting tests have shown that modular coupling generates a negligible amount of debris; the metal particles produced during a test which simulates 20 years of activity of an average patient is less than 2.4 mg* , i.e. half of that reported in literature for the modular necks currently available on the market and, in any case, certainly less than the quantity of particulate equal to 10 mg/year a stable prosthesis may be expected to produce ("Fretting wear in a modular neck prosthesis" Viceconti M., Baleani M., Squarzoni S., Toni A.)
On the basis of these studies it is possible to state that MODULA SC necks do not represent a weak point of the implant but guarantee the necessary mechanical resistance to the stresses these products are subjected to.





* Estimate obtained assuming that the seat realized in the prosthesis stem is damaged to the same extent as the neck cone, equal to 1.2mg after a test conducted at 3300N for 20 million cycles.

The 15 final MODULA SC necks can, in fact, be rotated as required to occupy 27 positions in space.
To facilitate use, the trial necks are realized in 27 types aligned on 3 matrices of 9 necks each.
Thus, the following groups are formed:

GROUP 1
YELLOW support 9 necks with:

YELLOW group with VERSION correction
LENGTH identification colour:
3 GREEN necks, 3 RED necks, 3 BLUE necks
OFFSET identification colour:
WHITE: 1 GREEN neck, 1 RED neck, 1 BLUE neck
GREY: 1 GREEN neck, 1 RED neck, 1 BLUE neck
BLACK: 1 GREEN neck, 1 RED neck, 1 BLUE neck

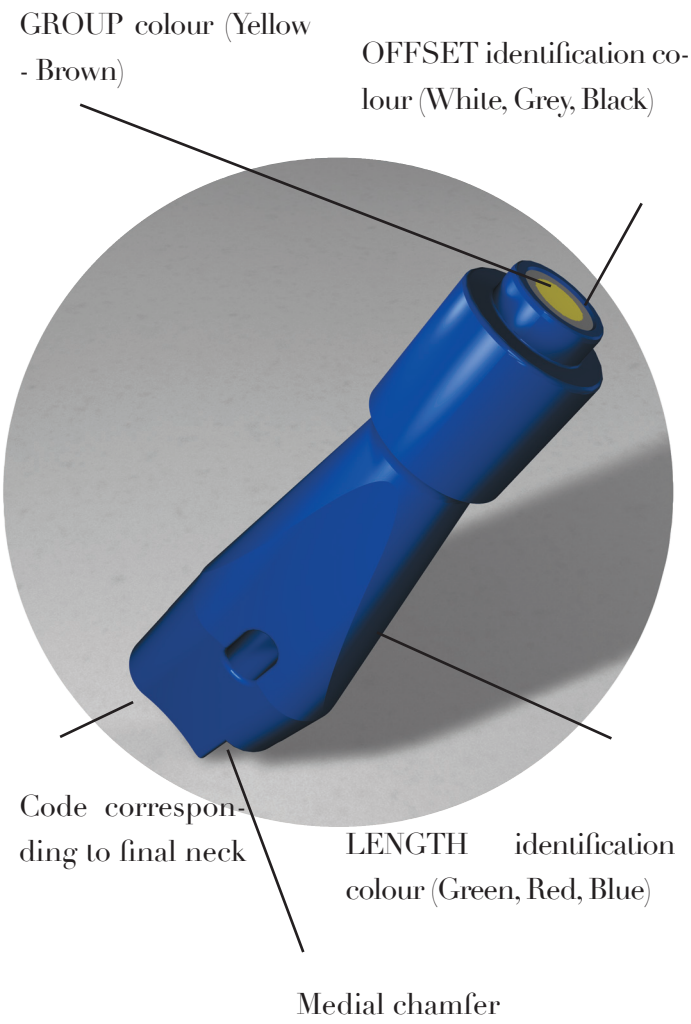
GROUP 0
WHITE support 9 necks:

No group colour
No VERSION correction
LENGTH identification colour:
3 GREEN necks, 3 RED necks, 3 BLUE necks
OFFSET identification colour:
WHITE: 1 GREEN neck, 1 RED neck, 1 BLUE neck
GREY: 1 GREEN neck, 1 RED neck, 1 BLUE neck
BLACK: 1 GREEN neck, 1 RED neck, 1 BLUE neck

GROUP 2
BROWN support 9 necks with:

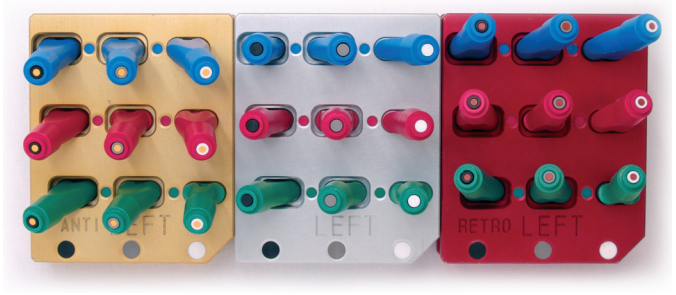
BROWN group
with VERSION correction
LENGTH identification colour:
3 GREEN necks, 3 RED necks, 3 BLUE necks
OFFSET identification colour:
WHITE: 1 GREEN neck, 1 RED neck, 1 BLUE neck
GREY: 1 GREEN neck, 1 RED neck, 1 BLUE neck
BLACK: 1 GREEN neck, 1 RED neck, 1 BLUE neck

NOTE: The three supports have cavities to house the trial necks on both fronts; the same 27 trial necks can be used to obtain the 27 spatial positions for both the femurs.



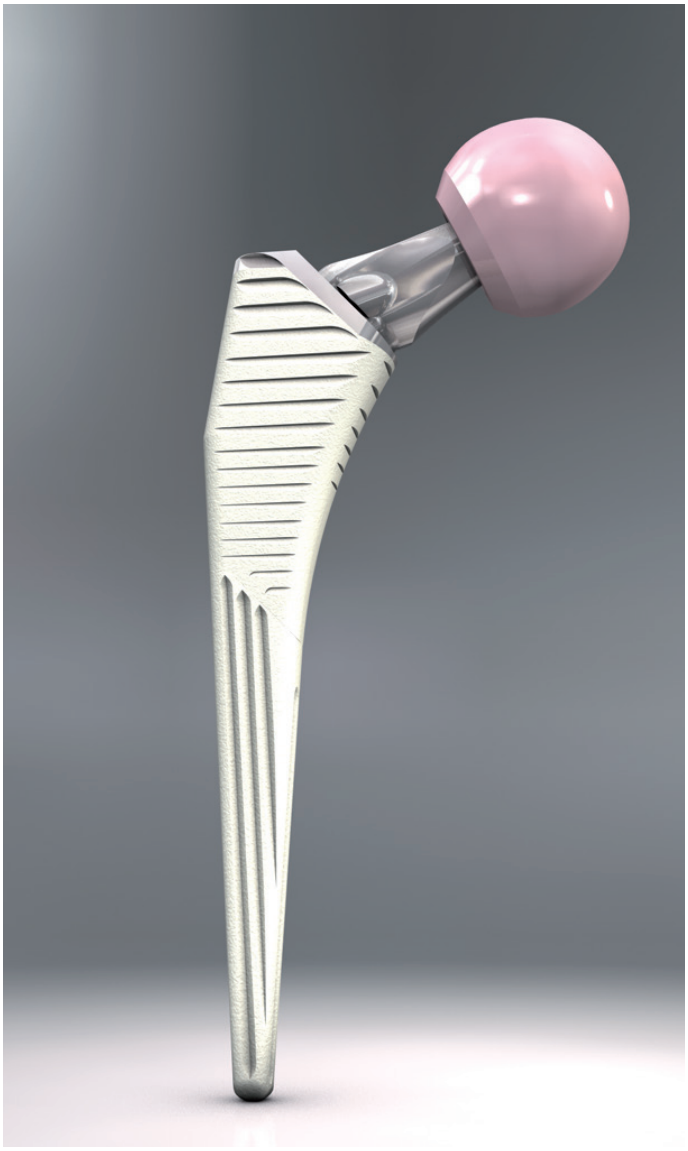
In the opposite part the supports are provided for the RH hip where the LH retroversion becomes RH anteversion and the LH anteversion becomes RH retroversion.

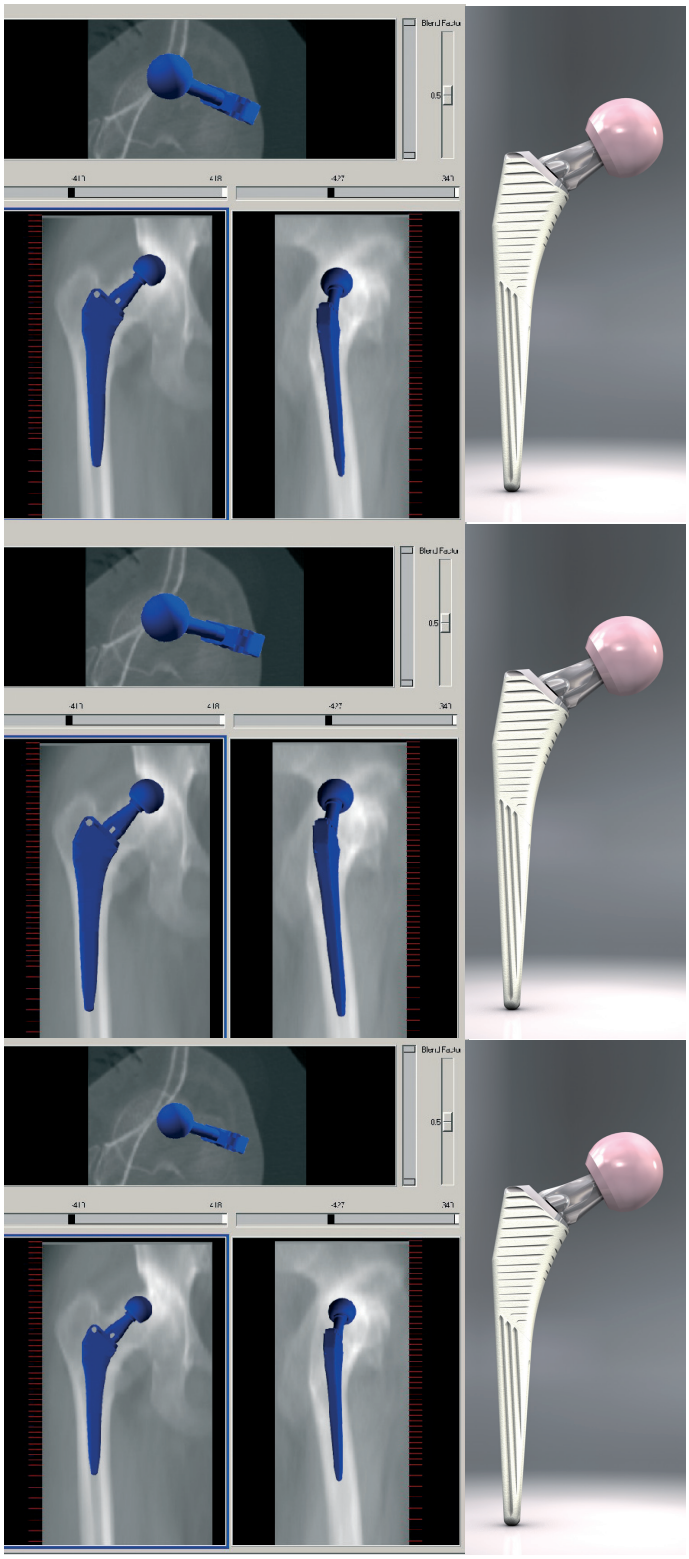
For example: Left hip



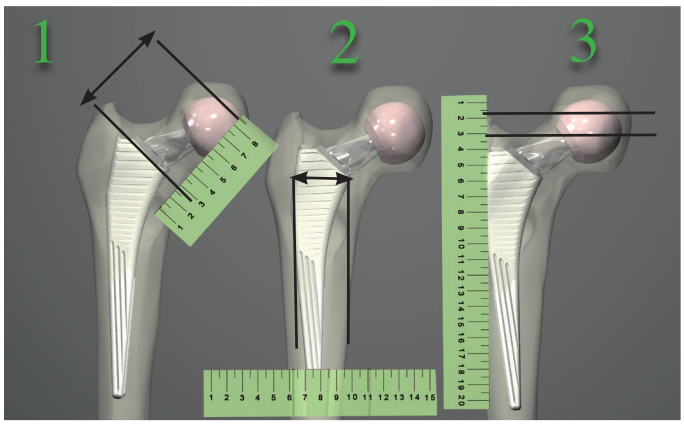
OPERATING TECHNIQUE

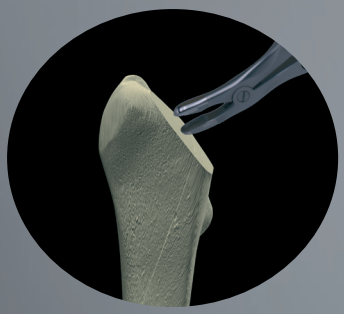
In the pre-operative planning, the stem size is selected by means of glossies or CT reconstruction and after the best stem position in the diaphyseal canal is identified, three measurements are taken:

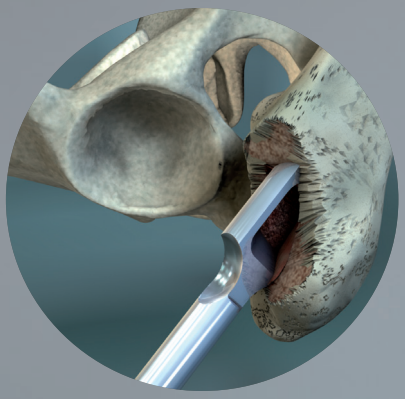




1 Length of femoral neck resection (can be measured from the proximal surface of the epiphysis or from the lesser trochanter).
2 Distance between the inner surface of the femoral cortex to the calcar and outer rasping limit.
3 Distance between the apex of the greater trochanter and upper edge of the stem.







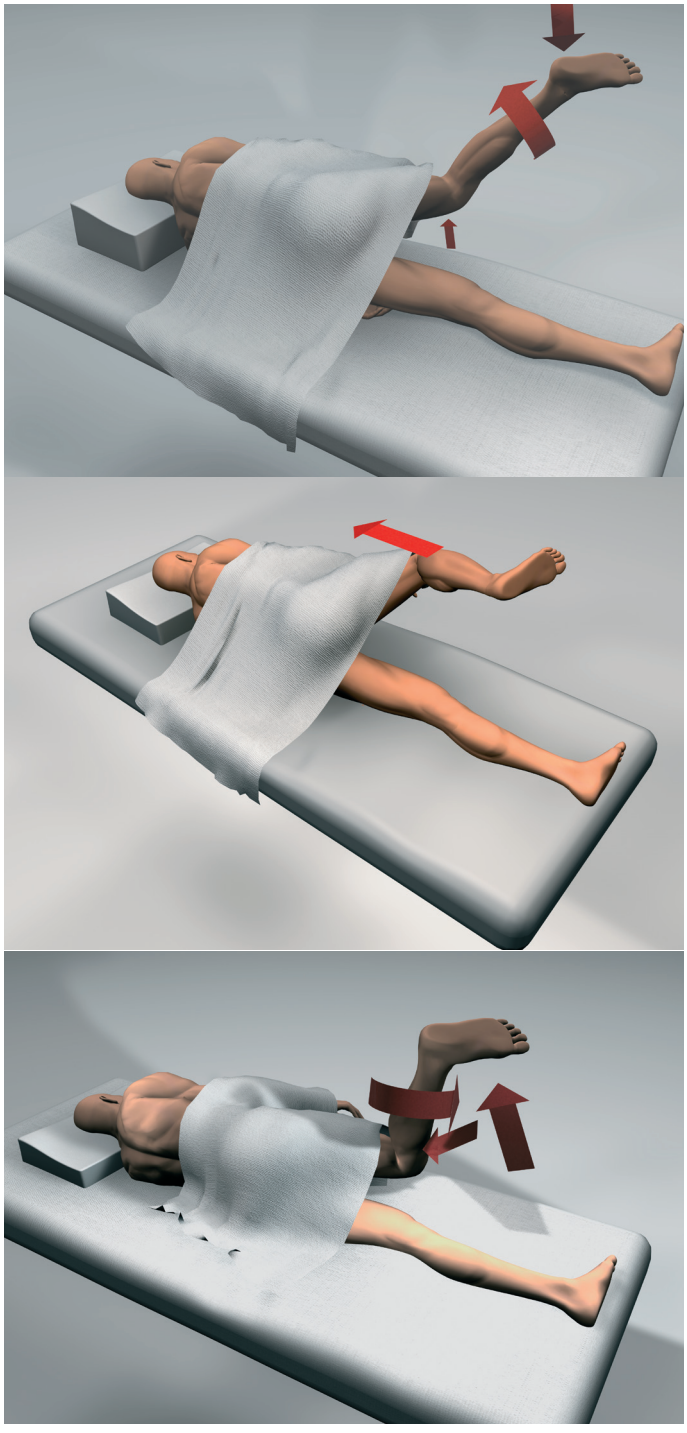
After luxation of the femoral epiphysis, the length of osteotomy of the neck is determined by measuring the amplitude of the epiphyseal surface, in relation to the system selected in the pre-operative plan.
The synovial tissue is cleared from the lateral-most surface of the osteotomic section of the femoral neck and the cortical part is resected by a few millimetres using the Luer forceps, in such a manner as to insert the box chisel aligning it with the diaphyseal axis.
Rasping is started by inserting the smaller rasps, taking care to force the rasp slightly towards the lateral edge of the neck to lateralize it to avoid varus positioning of the stem.
The procedure continues up to the final size defined in the pre-operative plan, always checking to make sure that during its progress the rasp does not tend to get jammed in the diaphyseal cavity; this can be done by simply twisting the rasp every time it sinks by 1 or 2 cm, checking to make sure there is still movement between the rasp and bone. If "jamming" occurs before the selected rasp reaches its seat, it is necessary to make sure the lateralization of the rasp corresponds to size "2" of the pre-operative plan. A few mm can favour the choice of an undersized stem and/or its insertion in varus.
The aim is to insert the rasp of the selected size to the predefined depth (size "3" of the pre-operative plan). The exact definition of this depth is obviously based on the resistance to its advancement; as a rule, if the rasp does not sink into the bone when hammered a few times, it must be considered as having reached its optimum penetration.

OPERATING TECHNIQUE

In complicated cases such as severe dysplasia, modular trial necks can be applied on the rasps to check to ensure correct reduction of the hip and its stability.
In normal cases, it is advisable to use the trial necks directly on the final stem since the latter may be positioned (although very slightly) differently from the rasp.
Having selected the size, the prosthesis is taken out of its sterile packing. By using the impactor extractor meant for the purpose (exploiting the clamp effect between the male neck) inserted in the stem cavity and the threaded handle which gets locked in the upper cavity, the prosthesis is inserted in its final position, always applying the rule of stopping if it advances no further when hammered three times. The sinking of the stem is then checked in relation to the apex of the greater trochanter and if it is found to be different from that calculated in the pre-operative plan, the choice of the neck and trial head must be adjusted to suit the stem position and the cup thus obtained.

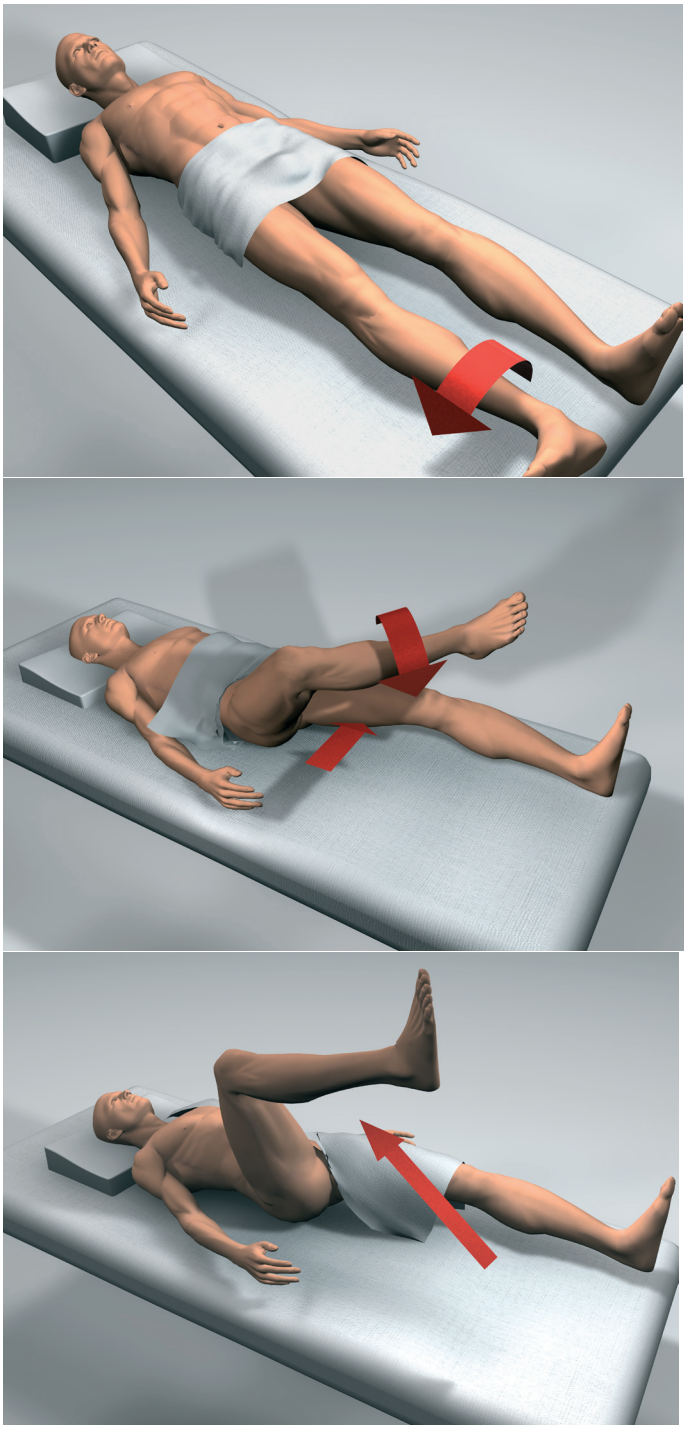
Then proceed with reduction of the prosthesis and check the length of the limb and stability of the prosthesis, making sure that the prosthesis is not dislocated in the following three positions:

ACCESS WAY POSTERO - LATERAL



1 - Extension by 10° + extra-rotation
2 - Bending 90° neutral
3 - Bending + maximum intra-rotation

ACCESS WAY ANTERO - LATERAL



1 - Extension on the bed plane + maximum extra-rotation
2 - Maximum adduction + extra-rotation
3 - Maximum bending

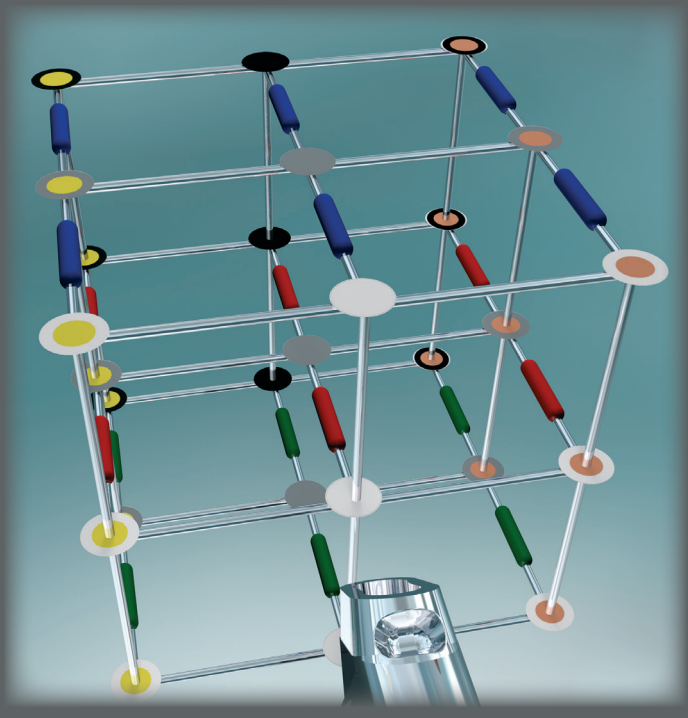
CHOICE OF NECK

This phase is the crucial moment of the operation.
The neck is, in fact, the extramedullary component which allows articulation between the femur and the acetabulum, establishing ideal anatomo-physiological conditions.
The MODULA SC necks act on three spatial variables length, offset and version independently and sequentially to minimize the possibility of error, particularly if pre-operative planning has been carried out correctly.
With MODULA SC necks, more than the best choice of the neck, it is important to select the best point in a 3-D matrix which makes it possible to solve the difficult equation of identification of the articular centre.

THE TRIAL NECKS COLOUR CODES KEY

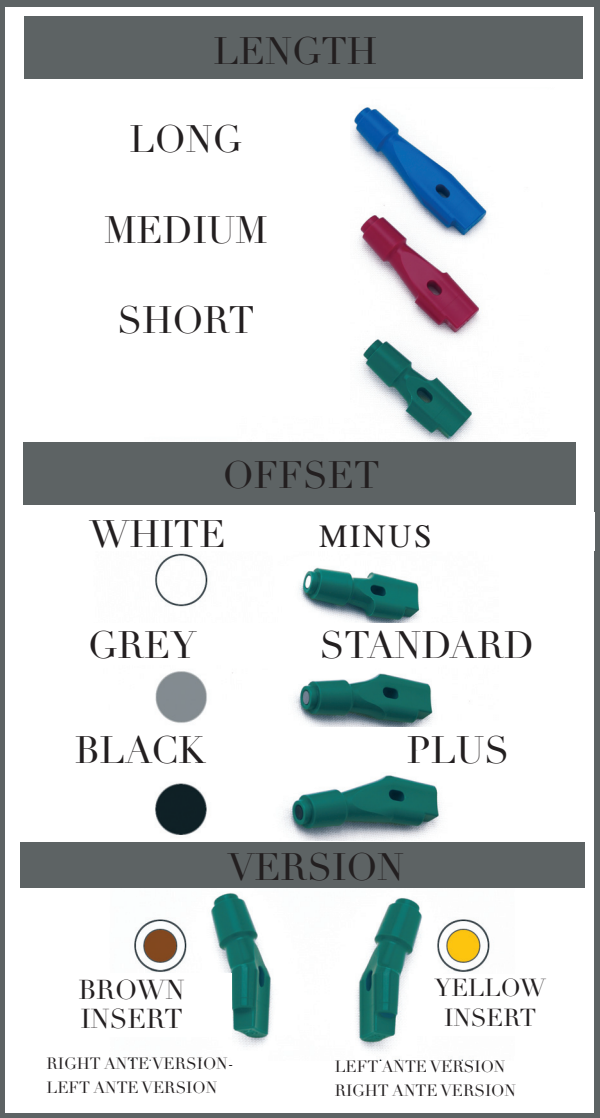
MODULA SC necks make it possible to reach 27 points in space and with heads available in 3 lengths, the real availability is 81 points over 3 dimensions for the right limb and an equal number for the left limb.
The final necks are 15 and help to achieve the objectives mentioned above.
To make the choice of the optimal neck much easier, 27 trial necks are used.
9 GREEN necks which will occupy the SHORT length line in three spatial matrices
9 RED necks which will occupy the MEDIUM length line in three spatial matrices
9 BLUE necks which will occupy the LONG length line in three spatial matrices
An identification colour is applied to each of the 27 necks, indicating that it belongs to one of the 3 OFFSET values, therefore, there will be:
3 GREEN necks; 3 RED necks and 3 BLUE necks for a total of 9 necks with identification colour WHITE to indicate the MINUS offset value
3 GREEN necks; 3 RED necks and 3 BLUE necks for a total of 9 necks with identification colour GREY to indicate the STANDARD offset value
3 GREEN necks; 3 RED necks and 3 BLUE necks for a total of 9 necks with identification colour BLACK to indicate the PLUS offset value.

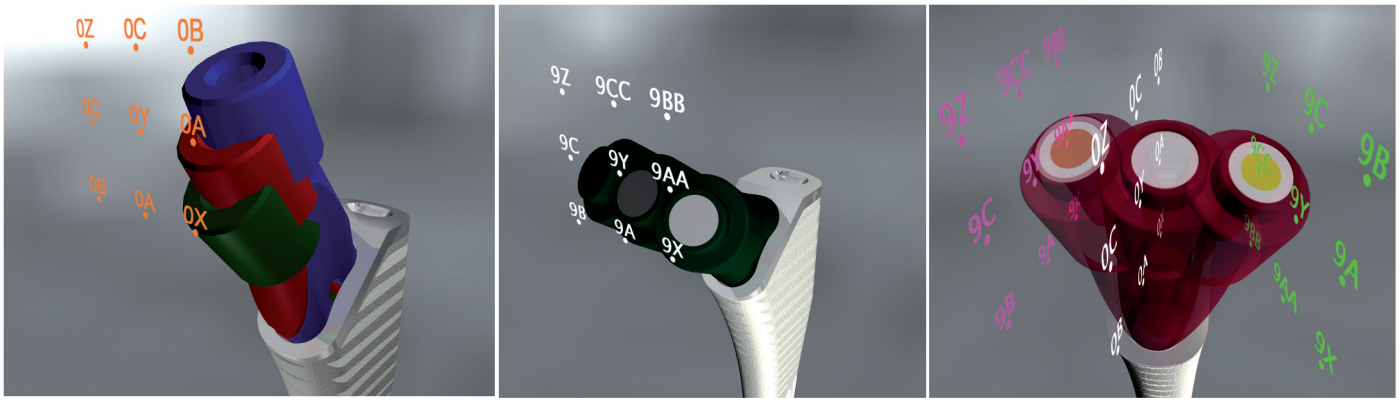
For example: Left hip



LENGTH
OFF-SET
VERSION

The 18 necks with VERSION correction are divided into two groups of 9 necks by means of two group colours YELLOW (GROUP 1) and BROWN (GROUP 2); the remaining 9 necks with ZERO version correction form GROUP 0.





PHASE 1

The first parameters to be defined are LENGTH and OFFSET
The trial necks which determine this parameter are the 9 necks present on the WHITE support and defined as necks belonging to GROUP 0 (zero anti-retroversion).
On the basis of the pre-operative plan, the neck considered as most suitable from among the 9 necks belonging to GROUP 0 on WHITE support is used first.
In the absence of a plan or in case of doubt regarding the choice of the neck, the central RED trial neck with GREY offset referred to as 0Y will be used first.
Obviously, apart from the possibilities offered by the necks available, it is possible to count on the various head lengths for further adjustments.

PHASE 2

Having identified the neck (from among the nine necks of GROUP 0) which offers the best combination of length and offset, it is possible to proceed, if necessary, for better stabilization of the joint, with the choice of the third spatial variable, the VERSION (ante and retro).
The latter is determined without modifying the parameters obtained earlier (length and offset) using the neck of the same colour (GREEN, RED, BLUE) and the same definition (WHITE, GREY, BLACK) of GROUP 1 present on YELLOW support, or GROUP 2 present on BROWN support.
NOTE: In case of the RH hip, the YELLOW colour (insert and support) indicates retroverse necks, while the BROWN colour (insert and support) indicates anteverse necks. It is the other way around for the LH hip. The Table/poster and 3-D model present in the instruments set can be useful.
Reference to correct positioning of the trial neck will facilitate insertion of the final neck. A special hourglass shaped bevelling of the trial neck, to be oriented always towards the medial part, will help the surgeon position the neck correctly.
Having identified the final neck, after washing it thoroughly, it is inserted in the stem by hammering with medium intensity.
Before inserting the final head identified by means of trial heads, the truncated-conical surface of the neck must be washed and dried.
If a ceramic head is used, it must be inserted with a 180° movement, avoiding hammering the head once it is in place. The dislocation is then reduced, which must be done without using the "reduction spoon".

IMPLANTS AND INSTRUMENTS

IMPLANTS

0107101	HYDRA STEM WO/CEM	SIZE 9	0187301	HYDRA STEM CEM.
0107102	HYDRA STEM WO/CEM	SIZE 10	0187302	HYDRA STEM CEM.
0107103	HYDRA STEM WO/CEM	SIZE 11	0187303	HYDRA STEM CEM.
0107104	HYDRA STEM WO/CEM	SIZE 12	0187304	HYDRA STEM CEM.
0107105	HYDRA STEM WO/CEM	SIZE 13	0187305	HYDRA STEM CEM.
0107106	HYDRA STEM WO/CEM	SIZE 14	0187306	HYDRA STEM CEM.
0107107	HYDRA STEM WO/CEM	SIZE 15	0187307	HYDRA STEM CEM.
0107108	HYDRA STEM WO/CEM	SIZE 16	0187308	HYDRA STEM CEM.
0107109	HYDRA STEM WO/CEM	SIZE 17		
0107110	HYDRA STEM WO/CEM	SIZE 18		

0514281	DELTA SHORT CERAMIC HEAD	D. 28	
0514282	DELTA MEDIUM CERAMIC HEAD	D. 28	
0514283	DELTA LONG CERAMIC HEAD	D. 28	
0514321	DELTA SHORT CERAMIC HEAD	D. 32	
0514322	DELTA MEDIUM CERAMIC HEAD	D. 32	
0514323	DELTA LONG CERAMIC HEAD	D. 32	
0514361	DELTA SHORT CERAMIC HEAD	D. 36	
0514362	DELTA MEDIUM CERAMIC HEAD	D. 36	
0514363	DELTA LONG CERAMIC HEAD	D. 36	
0514401	DELTA SHORT CERAMIC HEAD	D. 40	
0514402	DELTA MEDIUM CERAMIC HEAD	D. 40	
0514403	DELTA LONG CERAMIC HEAD	D. 40	

0524221	D. 22 mm	SHORT	Cr-Co-Mo HEAD 12/14 taper
0524222	D. 22 mm	MEDIUM	Cr-Co-Mo HEAD 12/14 taper
0524223	D. 22 mm	LONG	Cr-Co-Mo HEAD 12/14 taper
0520281	D. 28 mm	SHORT	Cr-Co-Mo HEAD 12/14 taper
0520282	D. 28 mm	MEDIUM	Cr-Co-Mo HEAD 12/14 taper
0520283	D. 28 mm	LONG	Cr-Co-Mo HEAD 12/14 taper
0524321	D. 32 mm	SHORT	Cr-Co-Mo HEAD 12/14 taper
0524322	D. 32 mm	MEDIUM	Cr-Co-Mo HEAD 12/14 taper
0524323	D. 32 mm	LONG	Cr-Co-Mo HEAD 12/14 taper
0524361	D. 36 mm	SHORT	Cr-Co-Mo HEAD 12/14 taper
0524362	D. 36 mm	MEDIUM	Cr-Co-Mo HEAD 12/14 taper
0524363	D. 36 mm	LONG	Cr-Co-Mo HEAD 12/14 taper

0460110	MODULA® NECK S.F.	12/14	0X
0460210	MODULA® NECK S.F.	12/14	0A
0460220	MODULA® NECK S.F.	12/14	0Y
0460310	MODULA® NECK S.F.	12/14	0B
0460320	MODULA® NECK S.F.	12/14	0C
0460330	MODULA® NECK S.F.	12/14	0Z
0469110	MODULA® NECK S.F.	12/14	9X
0469120	MODULA® NECK S.F.	12/14	9AA
0469130	MODULA® NECK S.F.	12/14	9BB
0469210	MODULA® NECK S.F.	12/14	9A
0469220	MODULA® NECK S.F.	12/14	9Y
0469230	MODULA® NECK S.F.	12/14	9CC
0469310	MODULA® NECK S.F.	12/14	9B
0469320	MODULA® NECK S.F.	12/14	9C
0469330	MODULA® NECK S.F.	12/14	9Z

INST RUMENTS

IB00000	HYDRA COMPLETE INSTRUMENT SET		
IC06500	CHISEL		
IB00109	HYDRA MODULAR RASP	SIZE 9	
IB00110	HYDRA MODULAR RASP	SIZE 10	
IB00111	HYDRA MODULAR RASP	SIZE 11	
IB00112	HYDRA MODULAR RASP	SIZE 12	
IB00113	HYDRA MODULAR RASP	SIZE 13	
IB00114	HYDRA MODULAR RASP	SIZE 14	
IB00115	HYDRA MODULAR RASP	SIZE 15	
IB00116	HYDRA MODULAR RASP	SIZE 16	
IB00117	HYDRA MODULAR RASP	SIZE 17	
IB00118	HYDRA MODULAR RASP	SIZE 18	
IB00200	HYDRA STEM HOLDER		
IC00220	EMERGENCY EXTRACTOR FOR RASPS		
IG03000	ALATA STEM IMPACTOR		
IG01000	HANDLE FOR ALATA STEMS IMPACTOR		
IC03200	TRS UNIVERSAL RASP-HOLDER HANDLE		
IC00400	STEM EXTRACTOR		
IM00100	BLUE TRIAL NECK WHITE CAP	0B	LONG
IM00200	BLUE TRIAL NECK GREY CAP	0C	LONG
IM00300	BLUE TRIAL NECK BLACK CAP	0Z	LONG
IM00400	RED TRIAL NECK WHITE CAP	0A	MEDIUM
IM00500	RED TRIAL NECK GREY CAP	0Y	MEDIUM
IM00600	RED TRIAL NECK BLACK CAP	0C	MEDIUM
IM00700	GREEN TRIAL NECK WHITE CAP	0X	SHORT
IM00800	GREEN TRIAL NECK GREY CAP	0A	SHORT
IM00900	GREEN TRIAL NECK BLACK CAP	0B	SHORT
IM01100	BLUE TRIAL NECK WHITE CAP YELLOW TIP	9B	LONG
IM01200	BLUE TRIAL NECK GREY CAP YELLOW TIP	9C	LONG
IM01300	BLUE TRIAL NECK BLACK CAP YELLOW TIP	9Z	LONG
IM01400	RED TRIAL NECK WHITE CAP YELLOW TIP	9A	MEDIUM
IM01500	RED TRIAL NECK GREY CAP YELLOW TIP	9Y	MEDIUM
IM01600	RED TRIAL NECK BLACK CAP YELLOW TIP	9CC	MEDIUM
IM01700	GREEN TRIAL NECK WHITE CAP YELLOW TIP	9X	SHORT
IM01800	GREEN TRIAL NECK GREY CAP YELLOW TIP	9AA	SHORT
IM01900	GREEN TRIAL NECK BLACK CAP YELLOW TIP	9BB	SHORT
IM02100	BLUE TRIAL NECK WHITE CAP RED TIP	9BB	LONG
IM02200	BLUE TRIAL NECK GREY CAP RED TIP	9CC	LONG
IM02300	BLUE TRIAL NECK BLACK CAP RED TIP	9Z	LONG
IM02400	RED TRIAL NECK WHITE CAP RED TIP	9AA	MEDIUM
IM02500	RED TRIAL NECK GREY CAP RED TIP	9Y	MEDIUM
IM02600	RED TRIAL NECK BLACK CAP RED TIP	9C	MEDIUM
IM02700	GREEN TRIAL NECK WHITE CAP RED TIP	9X	SHORT
IM02800	GREEN TRIAL NECK GREY CAP RED TIP	9A	SHORT
IM02900	GREEN TRIAL NECK BLACK CAP RED TIP	9B	SHORT
IM03100	GREY PLATE FOR RH/LH TRIAL NECKS		
IM03200	RED PLATE FOR RH ANTE/LH RETRO TRIAL NECKS		
IM03300	YELLOW PLATE FOR RH RETRO/LH ANTE TRIAL NECKS		
IM07701	“FORK” COMPONENT FOR NECKS EXTRACTOR		
IM07702	NECKS EXTRACTOR BEATER		
IM07704	“FORK” COMPONENT FOR NECKS EXTRACTOR H 2mm		
IH28000	TRIAL HEAD	D. 28	SHORT
IH28100	TRIAL HEAD	D. 28	MEDIUM
IH28200	TRIAL HEAD	D. 28	LONG
IH32000	TRIAL HEAD	D. 32	SHORT
IH32100	TRIAL HEAD	D. 32	MEDIUM
IH32200	TRIAL HEAD	D. 32	LONG
IH36400	TRIAL HEAD	D. 36	SHORT
IH36500	TRIAL HEAD	D. 36	MEDIUM
IH36600	TRIAL HEAD	D. 36	LONG
IH40000	TRIAL HEAD	D. 40	SHORT
IH40100	TRIAL HEAD	D. 40	MEDIUM
IH40200	TRIAL HEAD	D. 40	LONG

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