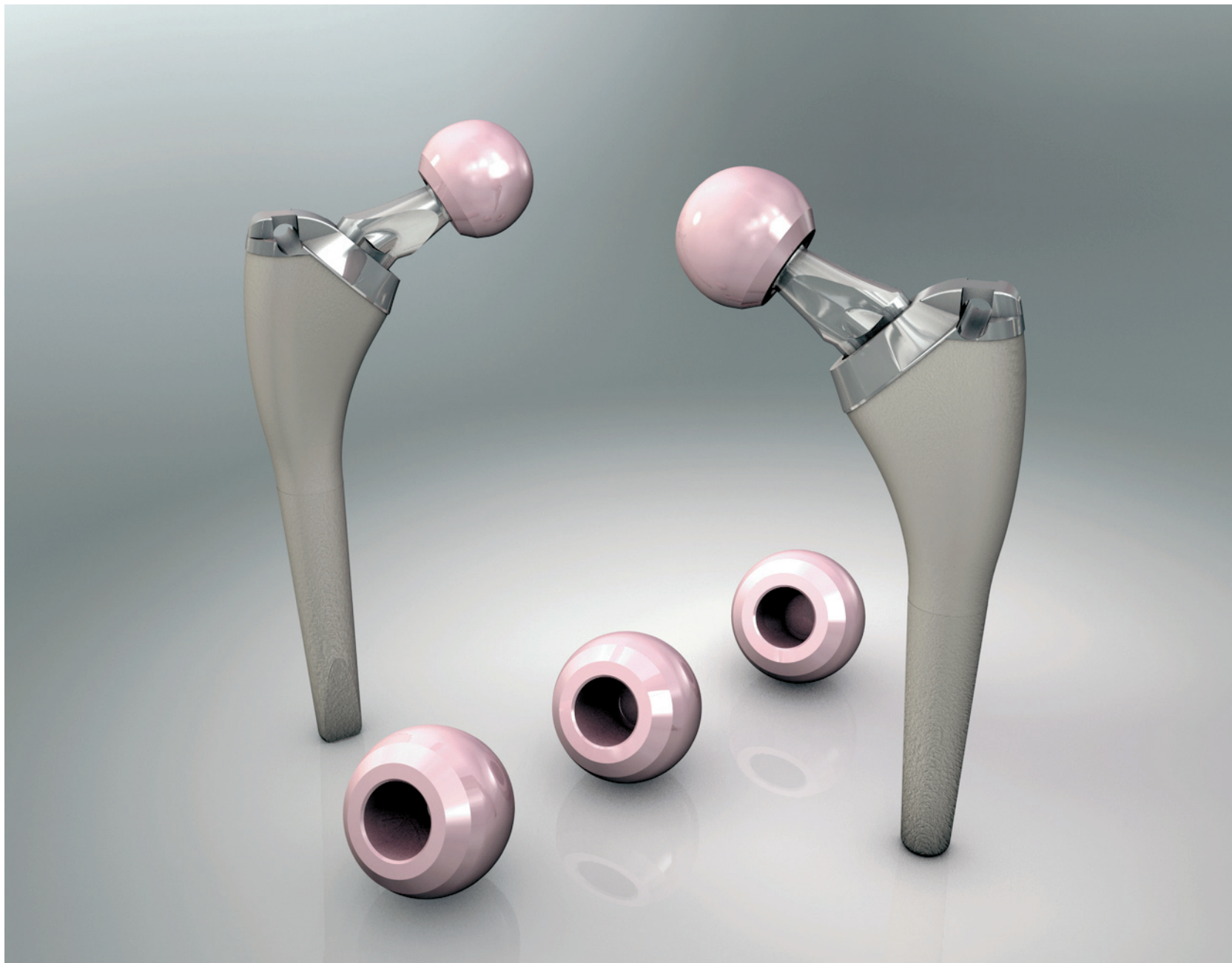




APTA



 **ADLER**[®]
ORTHO

Apta

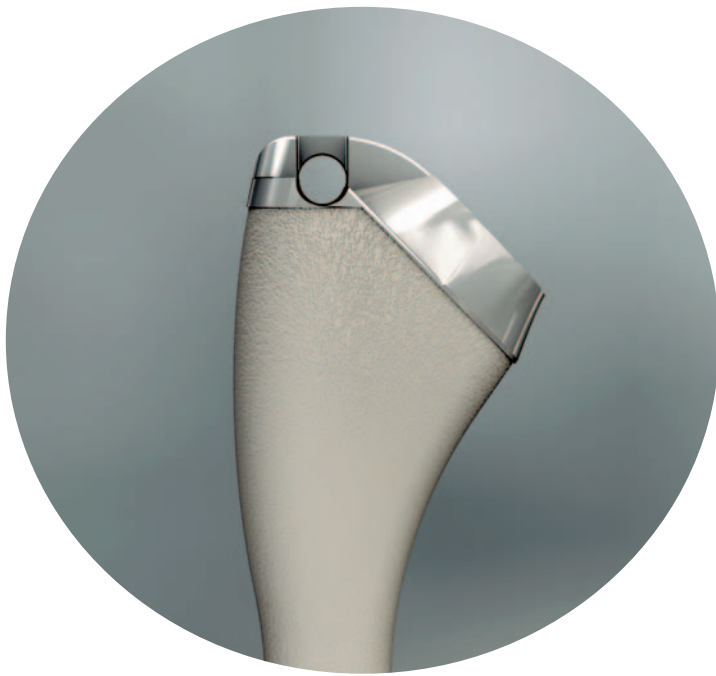


The APTA stem, available in eight sizes for the right and eight for the left femur, has been designed upon morphological studies of the size and dimensions of the femur based on CAT scans of hundreds of patients. The statistical techniques and elaboration on the PC have made it possible to construct a press-fit endomedullary stem component, which has the exclusive function of anchoring to the host femur using optimum filling in the metaphyseal as well as the diaphyseal part, thereby guaranteeing correct adaptation to most femoral diaphysis. This press-fit structure is necessary to allow correct insertion and positioning of the stem and, with a stable proximal support between the calcar region and greater trochanter to facilitate secondary osteointegration.

The stem, made of titanium alloy (Ti6Al4V ISO 5832/3 ASTM F136) has passed the tests envisaged by specific ISO 7206/4 and ISO 7206/B standards.

An accurate specific study has made it possible to optimize the 400-micron porous titanium coating limited to the proximal region where bone integration is fundamental for stabilization of the stem.

The plasma spray technique involving application of heated titanium powder allows considerable adherence of materials. The 50-micron hydroxyapatite coating (in conformity to ASTM standard F1185) along the stem facilitates bone formation all around the prosthesis, reducing risk of radiographic radiolucence.



- 1 Positioning of a stem-holder and initial insertion system using the special disposable device
- 2 Housing the final impactor-guide
- 3 Insertion of extraction hook.

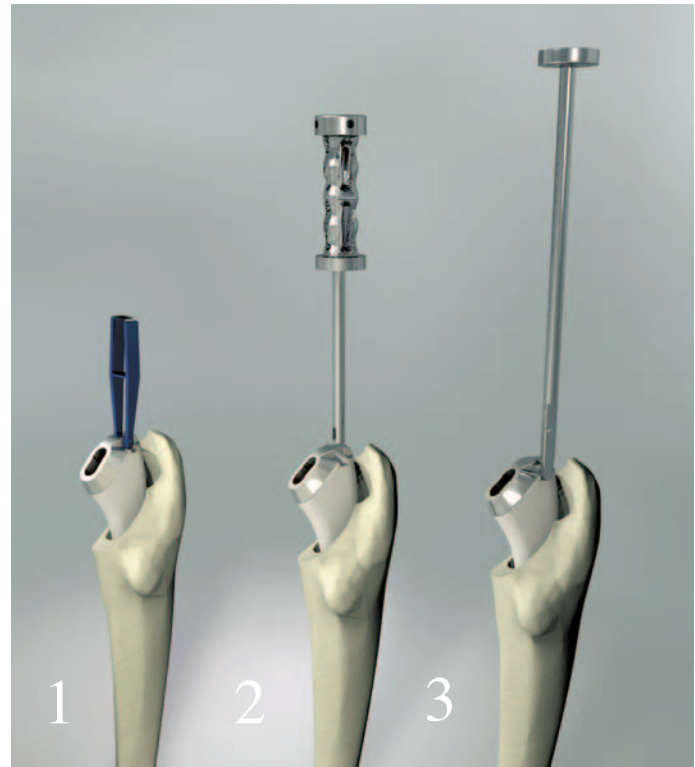
The stem is also available in the version with collar, which extends mainly along the medial area.

- The stem meant for use without cement has the same features as the version without collar.



The stem is short and has a smoothed tip to minimize the “pointed” effect responsible for thigh pain.

The stem has a hole in the proximal part near the greater trochanter for



- The stem meant for use with cement is completely smooth with “mirror” polish to limit abrasion and breakage of the cement.

The collar makes it possible to increase pressurization of the acrylic cement in the stem implant phase.

MODULAR NECKS

Over the last 20 years, orthopaedic surgery has seen very little significant conceptual evolution: one of these is, undoubtedly, the modularity of the extramedullary component (neck) of a hip arthroprosthesis.

Thanks to this possibility, a standard implant can be adapted to different anatomical-physiological characteristics of a patient without affecting correct positioning, thereby offering greater possibility of stability over time of the stem and cup, and without using excessively large sizes. The complete series of MODULA necks, consisting of 15 pieces (all our patents), allows customization of the position of the other two components to the articulation needs of the patient, and restoration of the correct length and offset.

So what are the reasons that have induced us to continue with the research for other innovative solutions for 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 last few years in the number of over-weight patients.

Thanks to the wide spatial coverage of MODULA necks, the operated patient can once again carry out the physiological movements that were possible 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.

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 for us to measure the stress in extreme conditions and indicate to us where and how to act to be able to design a specific instrument most suitable for such patients. We thus managed to design the MODULA SUPER CHARGED (SC) necks, meant for those who, because of their weight and type of activity, or simply for greater freedom of movement, can increase the stresses on the femoral neck to levels far greater than those that were considered as average to date.

The new MODULA SC necks with their anterior-posterior reinforcing fins, also useful as a system of removal of the neck from its seat in the stem, can amply satisfy the most demanding requisites, more brilliantly than other solutions, as has been proved by laboratory tests.

MODULA necks solve different kinds of problems

GEOMETRIC SOLUTION TO CLINICAL PROBLEMS

The spatial matrix allows regulation of the three main parameters:

LENGTH - OFFSET - VERSION

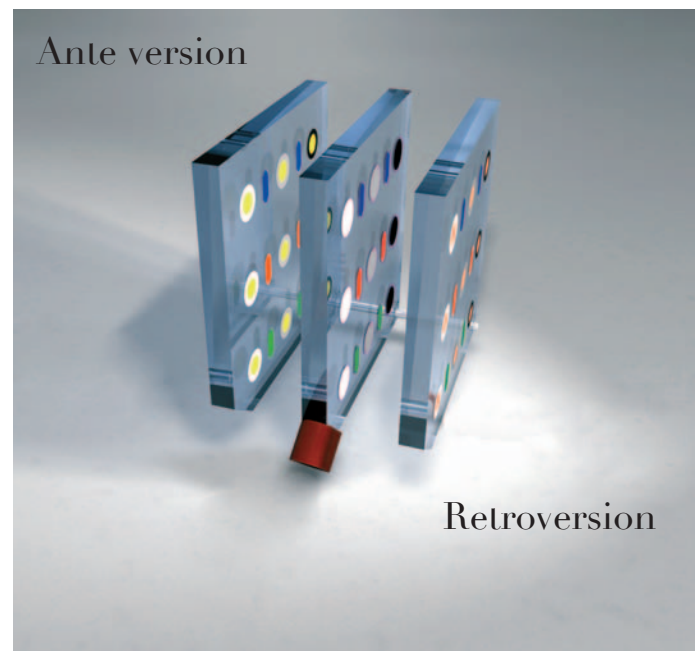
Independently of one another, sequentially and during the various phases of the operation - from preoperative planning to actual surgery.

To obtain this, it was necessary to give

up the policy of using angled necks with the LONG neck and SHORT neck versions, both as regards VARUS/VALGUS and ANTERO/RETROVERSION and realize necks of such length and inclination so that each occupies a predefined position in a point on a 3D matrix.

Extraction in axis guaranteeing extractability (separation of neck from stem) is fundamental to be able to use all the features of mobile necks. Our patented extraction method, using the special slot made on all necks, makes it possible to ALWAYS work on the same plane (also on angled necks) and the extraction force is concentrated on two planes.

For example: Left hip



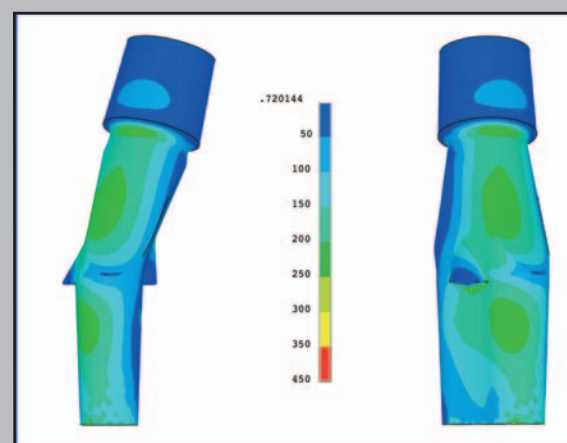
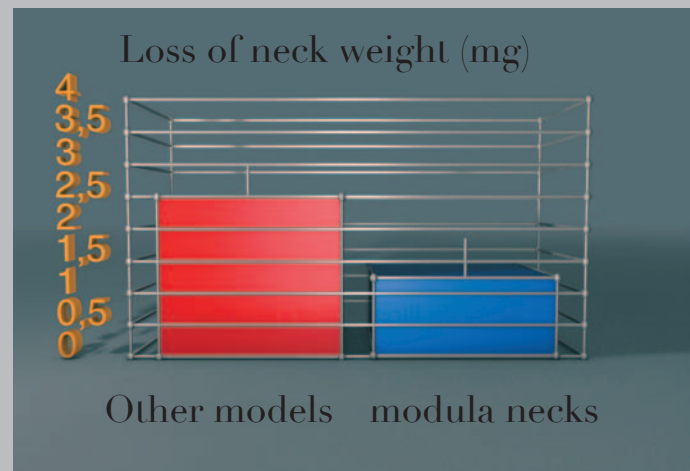


MECHANICAL SOLUTION TO RESISTANCE PROBLEMS

The hourglass shape with double elongated taper is designed to ensure anchoring to the two components exactly where required, i.e. in those areas that offer the greatest resistance to force. The drawing of the coupling is developed and validated for the successive phases:

- 1 Numerous studies have made it possible to optimize the hourglass shape of the tapered joint and the shape of the neck extraction slot to reduce mechanical stresses in coupling, when the implant is subjected to physiological loads.
- 2 Fatigue tests have shown that even the most critical configuration can resist a cyclic load 50% greater than the limit value defined by the international ISO standards applicable.
- 3 Fretting tests have shown that the modular coupling generates negligible amount of debris, since the metal particulate produced in a test which

simulates 20 years of use by a patient is less than 2.4mg*, i.e. half of that recorded in literature for modular necks presently available on the market, and is, in any case, less than the quantity of particulate that may be produced by a normal stable prosthesis, estimated at 10mg/year (from “Fretting wear in a modular neck hip prosthesis” Viceconti M., Squarzoni S., Toni A.) Based on the studies it may be stated that the MODULA necks do not represent a weak point of the implant, while they guarantee the necessary mechanical resistance to stresses these products are subjected to.



*Estimate obtained by assuming that the seating in the prosthetic stem is damaged to the same extent as the neck taper, calculated as 1.2 mg, after a test conducted at 3300N for 20 million cycles.

The three spatial matrices are obtained by aligning the 27 trial necks on three supports, each capable of housing nine necks.

Thus the following groups are formed:

GROUP 1, YELLOW support 9 necks with:

- YELLOW group colour with VERSION correction

- LENGTH identification colour:

Three GREEN necks, 3 RED necks, 3 BLUE necks

- OFFSET identification colour

WHITE: one GREEN neck, one RED neck, 1 BLUE neck

GREY: one GREEN neck, one RED neck, 1 BLUE neck

BLACK: one GREEN neck, one RED neck, 1 BLUE neck

GROUP 0, WHITE support 9 necks:

- No group colour no VERSION correction

- With LENGTH identification colour:

Three GREEN necks, 3 RED necks, 3 BLUE necks

- With OFFSET identification colour

WHITE: one GREEN neck, one RED neck, 1 BLUE neck

GREY: one GREEN neck, one RED neck, 1 BLUE neck

BLACK: one GREEN neck, one RED neck, 1 BLUE neck

GROUP 2, BROWN support 9 necks with:

- BROWN group colour with VERSION correction

- With LENGTH identification colour:

Three GREEN necks, 3 RED necks, 3 BLUE necks

- OFFSET identification colour

WHITE: one GREEN neck, one RED neck, 1 BLUE neck

GREY: one GREEN neck, one RED neck, 1 BLUE neck



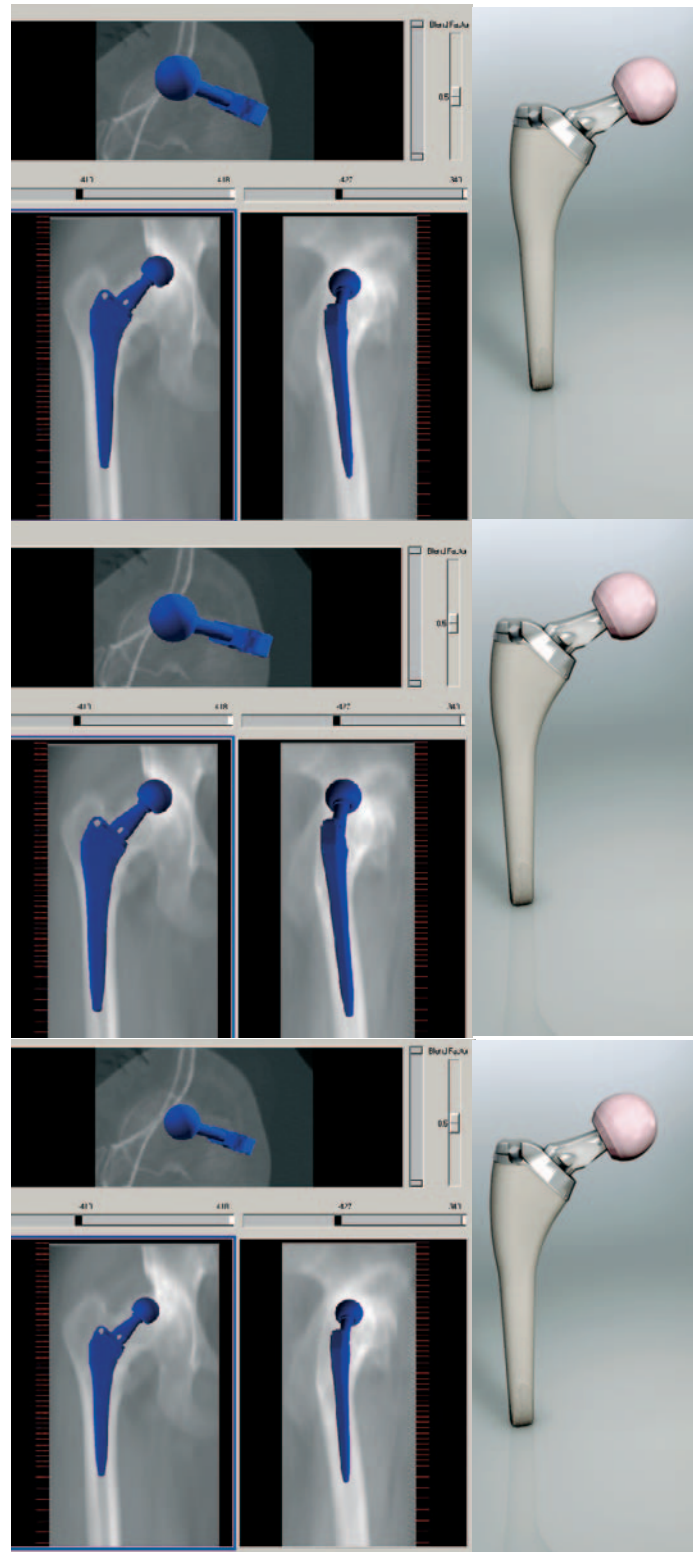
NB: The three supports have cavities on both faces for housing the trial necks; the same 27 necks can be used to obtain the 27 positions in space for both femurs.

For example: Left hip

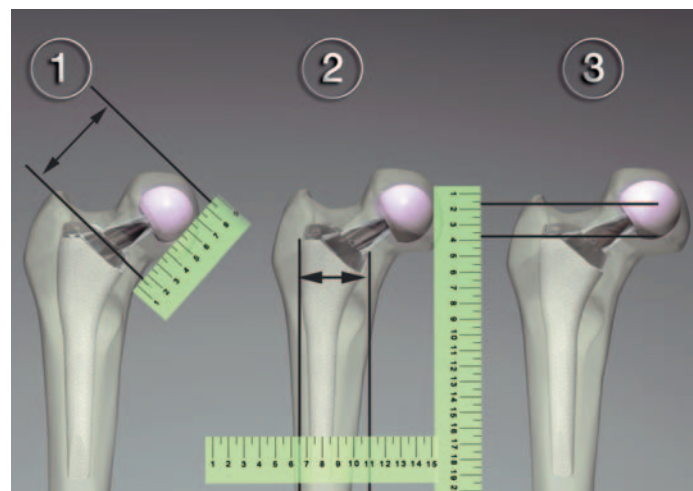


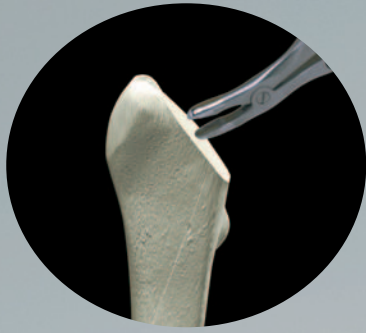
OPERATING TECHNIQUE

In the preoperative planning phase, the stem size is selected based on special templates or C.T. reconstruction, and after defining the best position in the diaphyseal canal, three measurements are made:



- 1 Length of resection of the femoral neck (it can be measured from the proximal surface of the epiphysis, or from the lesser trochanter).
- 2 Distance between the internal surfaces of femoral cortex at the calcar and the outer reaming limit.
- 3 Distance between the apex of the greater trochanter and upper stem edge.





After dislocation of the femoral epiphysis, the length of the osteotomy of the neck is based on the preoperative planning measure. The lateral-most surface of the osteotomic section of the femoral neck is cleaned to remove all synovial tissue that may be present, and the cortical part is resected by a few millimetres using a Luer rongeur, to make it possible to insert the encased scalpel aligning it with the diaphyseal axis.

Flexible diaphyseal reamers may be used to check if the size of the diaphyseal canal corresponds to that measured in the preoperative template. It must be remembered that the reamer diameter must be identical to that of the final rasp selected, measured at a distance of 30mm from the stem distal tip.

Rasping then begins by inserting the smaller rasp, taking care to push it slightly against the sides of the neck for lateralization, to prevent varus positions of the stem.

The procedure thus continues until the size defined in the preoperative template is obtained, always checking to make sure the rasp does not get jammed in the diaphyseal cavity as it moves forward down: for this purpose, it is sufficient to twist the rasp as it goes deeper to make sure there is movement between the rasp and the bone. If there is “jamming” before the selected rasp reaches its seat, it is



necessary to verify that the rasp lateralization corresponds to size “2” of the preoperative template. A few mm can lead to the choice of an undersized stem inserted in varus!

The aim is to insert the rasp of the selected size to the predefined depth (size “3” of the preoperative template): the definition of the exact depth to which the reamer must be embedded is obviously based on the resistance offered to its insertion: the rule of the thumb is that if the rasp does not move further inwards after a few taps with the mallet, it must be considered as having reached its optimum depth.



In complex cases, such as for example in the case of severe dysplasia, trial modular necks can be applied on the rasp to check the possibility of reducing dislocation of the hip, as well as its stability.

In normal cases, it is advisable to carry out trials on the final stem, which, although it can itself change its position with respect to the broach to a very limited extent, will in any case, require the repetition of the trials with modular necks.

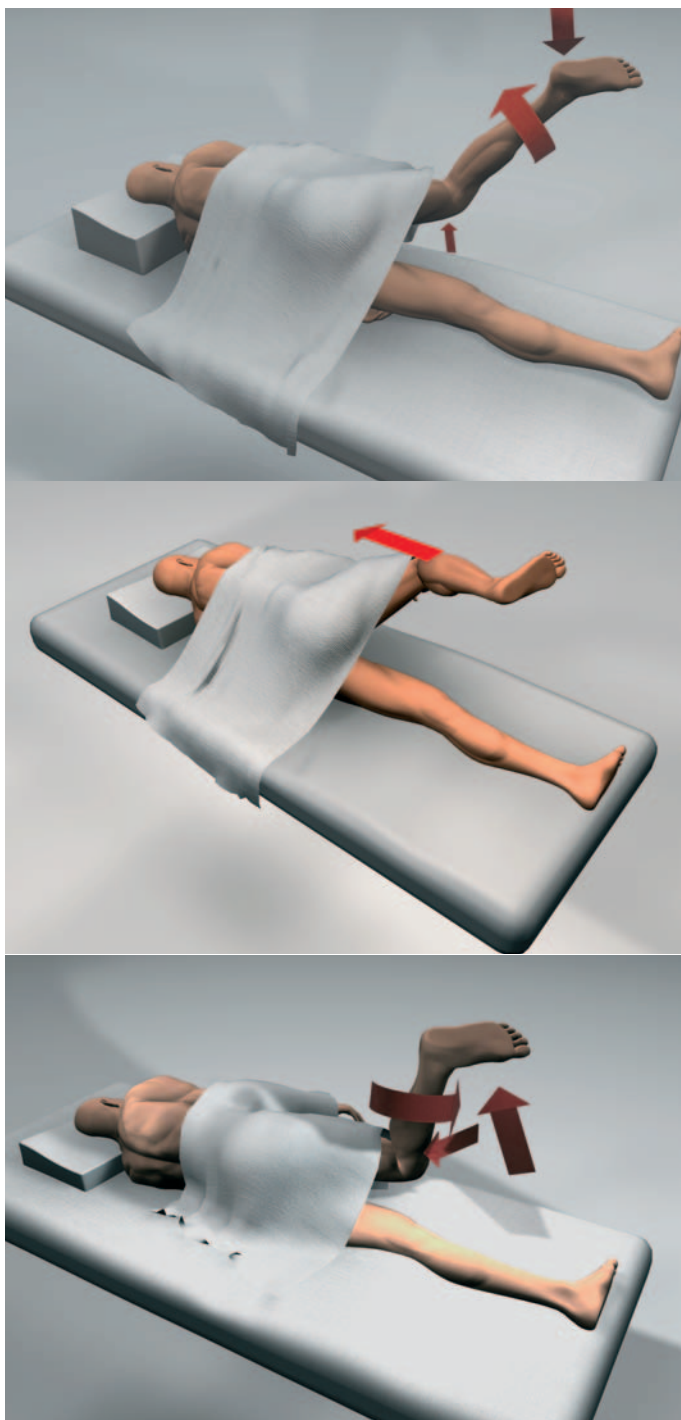


Once the prosthesis is chosen, it is removed directly from the sterile pack, using the special disposable plastic stem-holder and the stem is hand-inserted in the femur until it is blocked. A metal impactor tool is then used to insert the stem into its final position, and the hammering must stop when it is seen that the stem proceeds no further after three taps with the mallet. The depth of insertion of the stem is checked with respect to the tip of the greater trochanter: if it is different from that calculated in the preoperative template, the choice of neck and the trial head, which were defined in the template, must be adjusted based on the position of the stem and the cup.



Then carry out reduction of the prosthesis and check the length of the limb and the stability of the prosthesis; in order to do so, check to make sure the prosthesis does not dislocate in the following three positions (through the antero-lateral approach):

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

It will thus be possible to select the modular neck and head suitable for restoring the length, offset and stability in each case.

CHOICE OF NECK

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

LEGEND OF COLOUR CODES IN TRIAL NECKS

MODULA necks make it possible to reach 27 points in space and, as they have three head lengths, 81 points are actually available in three dimensions for the right limb and an equal number for the left limb.

Thanks to the 15 final necks available, it is possible to achieve the above-mentioned objectives. To simplify the choice of the optimum neck, 27 trial necks can be used. These 27 necks are made of plastic, in three different colours, i.e.:

Nine GREEN necks, which will occupy the SHORT length, line in the three spatial matrices

Nine RED necks, which will occupy the MEDIUM length, line in the three spatial matrices

Nine GREEN necks, which will occupy the LONG length, line in the three spatial matrices

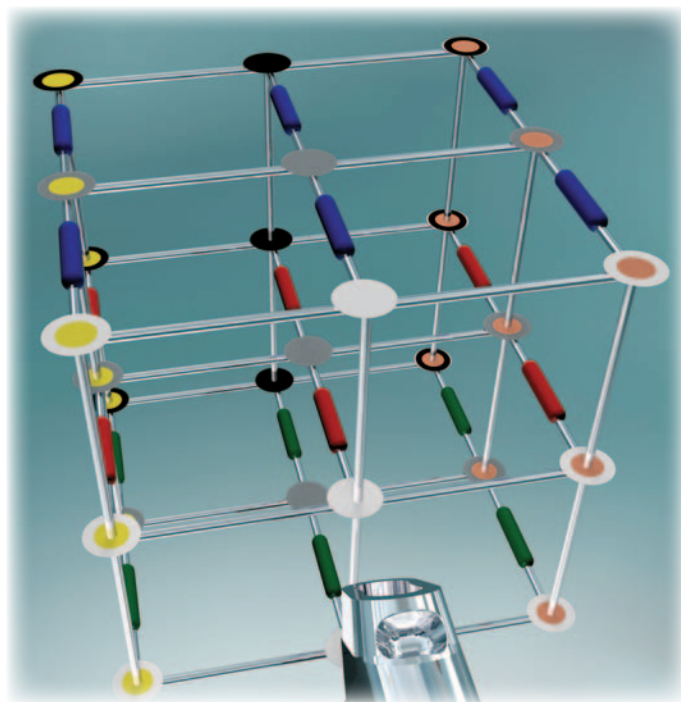
An identification colour is applied to each of these 27 necks to indicate one of the three OFFSET values to which they belong. Therefore, there will be:

(Three GREEN necks, 3 RED necks and three BLUE necks) nine pcs. With identification colour WHITE to indicate MINUS offset value

(Three GREEN necks, 3 RED necks and three BLUE necks) nine pcs. With identification colour GREY to indicate, STANDARD offset value

(Three GREEN necks, 3 RED necks and three BLUE necks) nine pcs. With identification, colour BLACK to indicate PLUS offset value

For example: Left hip

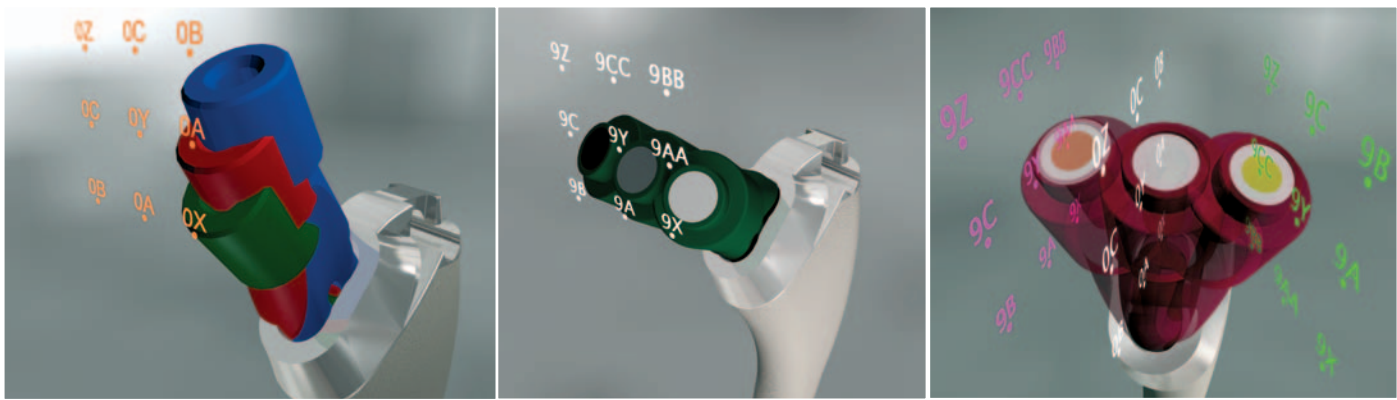




**LENGTH
OFF-SET
VERSION**

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

LENGTH	
LONG	
MEDIUM	
SHORT	
OFFSET	
○	
WHITE	MINUS
●	
GREY	STANDARD
●	
BLACK	PLUS
VERSION	
●	
BROWN INSERT	
	●
	YELLOW INSERT
RIGHT ANTEVERSION- LEFT ANTEVERSION	LEFT ANTEVERSION RIGHT ANTEVERSION



PHASE 1

The initial parameters to be defined are the LENGTH and the OFFSET. The trial necks, which determine these two parameters, are the nine necks present on WHITE support and defined as GROUP 0 necks (zero ante-retroversion). Depending on the preoperative templating, begin by using the neck considered most suitable from among the nine necks in GROUP 0 present on WHITE support. In the absence of a template or in case of doubt regarding the choice of neck, the operation begins by using the RED central trial neck with GREY offset referred to as 0Y.

Obviously, apart from the possibilities offered by the necks available, it is possible to depend on the different lengths of the heads, for further adjustments.

PHASE 2

After identifying the neck (from among the nine trial necks of GROUP 0) which offers the best combination of length and offset, it is possible to pass on to the choice of the third spatial variable, the VERSION (ante and retro), if necessary, for better stabilization of articulation.

The latter is determined without modifying the parameters obtained previously (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 a right hip, YELLOW (insert and support) indicates retroverted necks, while BROWN (insert and support) indicates anteverted necks. The opposite is the case for a left hip.

The table/poster and the 3D model included in the set of instruments can be very useful.

Reference to the correct position of the trial neck will facilitate insertion of the final neck. A suitable chamfer on the hourglass taper of the trial neck, to be oriented always towards the medial part, will help the surgeon position the neck correctly.

After identifying the final neck and washing the stem cavity thoroughly, it is inserted in the stem by hammering with medium force. Before inserting the final head, identified thanks to the trial heads, the truncated-conical surface of the neck must be washed.

If a ceramic head is used, it must be inserted by turning through 180°, avoiding hammering it once it is seated. Then luxation is reduced, which must be done without the aid of a hook.

IMPLANTS AND INSTRUMENTS

0101101	APTA STEM W./CEM. TI=HA TG. 1 R	0540363	HEAD METAL/METAL D. 36 LONG
0101102	APTA STEM W./CEM. TI=HA TG. 2 R	0540401	HEAD METAL/METAL D. 40 SHORT
0101103	APTA STEM W./CEM. TI=HA TG. 3 R	0540402	HEAD METAL/METAL D. 40 MEDIUM
0101104	APTA STEM W./CEM. TI=HA TG. 4 R	0540403	HEAD METAL/METAL D. 40 LONG
0101105	APTA STEM W./CEM. TI=HA TG. 5 R	0522221	HEAD CR. CO. D. 22 SHORT
0101106	APTA STEM W./CEM. TI=HA TG. 6 R	0522222	HEAD CR. CO. D. 22 MEDIUM
0101107	APTA STEM W./CEM. TI=HA TG. 7 R	0522223	HEAD CR. CO. D. 22 LONG
0101108	APTA STEM W./CEM. TI=HA TG. 8 R	0520281	HEAD CR. CO. D. 28 SHORT
0101111	APTA STEM W./CEM. TI=HA TG. 1 L	0520282	HEAD CR. CO. D. 28 MEDIUM
0101112	APTA STEM W./CEM. TI=HA TG. 2 L	0520283	HEAD CR. CO. D. 28 LONG
0101113	APTA STEM W./CEM. TI=HA TG. 3 L		
0101114	APTA STEM W./CEM. TI=HA TG. 4 L		
0101115	APTA STEM W./CEM. TI=HA TG. 5 L		
0101116	APTA STEM W./CEM. TI=HA TG. 6 L		
0101117	APTA STEM W./CEM. TI=HA TG. 7 L		
0101118	APTA STEM W./CEM. TI=HA TG. 8 L		
0181201	STEM APTA W./CEM. W/COL. TG. 1 R		
0181202	STEM APTA W./CEM. W/COL. TG. 2 R		
0181203	STEM APTA W./CEM. W/COL. TG. 3 R		
0181204	STEM APTA W./CEM. W/COL. TG. 4 R		
0181205	STEM APTA W./CEM. W/COL. TG. 5 R		
0181206	STEM APTA W./CEM. W/COL. TG. 6 R		
0181207	STEM APTA W./CEM. W/COL. TG. 7 R		
0181208	STEM APTA W./CEM. W/COL. TG. 8 R		
0181211	STEM APTA W./CEM. W/COL. TG. 1 L		
0181212	STEM APTA W./CEM. W/COL. TG. 2 L		
0181213	STEM APTA W./CEM. W/COL. TG. 3 L		
0181214	STEM APTA W./CEM. W/COL. TG. 4 L		
0181215	STEM APTA W./CEM. W/COL. TG. 5 L		
0181216	STEM APTA W./CEM. W/COL. TG. 6 L		
0181217	STEM APTA W./CEM. W/COL. TG. 7 L		
0181218	STEM APTA W./CEM. W/COL. TG. 8 L		
0101201	APTA STEM W./CEM. TI=HA W/COLLAR TG. 1 R	IH28000	TRIAL HEAD D. 28 SHORT
0101202	APTA STEM W./CEM. TI=HA W/COLLAR TG. 2 R	IH28100	TRIAL HEAD D. 28 MEDIUM
0101203	APTA STEM W./CEM. TI=HA W/COLLAR TG. 3 R	IH28200	TRIAL HEAD D. 28 LONG
0101204	APTA STEM W./CEM. TI=HA W/COLLAR TG. 4 R	IH32000	TRIAL HEAD D. 32 SHORT
0101205	APTA STEM W./CEM. TI=HA W/COLLAR TG. 5 R	IH32100	TRIAL HEAD D. 32 MEDIUM
0101206	APTA STEM W./CEM. TI=HA W/COLLAR TG. 6 R	IH32200	TRIAL HEAD D. 32 LONG
0101207	APTA STEM W./CEM. TI=HA W/COLLAR TG. 7 R	IH36400	TRIAL HEAD D. 36 SHORT
0101208	APTA STEM W./CEM. TI=HA W/COLLAR TG. 8 R	IH36500	TRIAL HEAD D. 36 MEDIUM
0101211	APTA STEM W./CEM. TI=HA W/COLLAR TG. 1 L	IH36600	TRIAL HEAD D. 36 LONG
0101212	APTA STEM W./CEM. TI=HA W/COLLAR TG. 2 L	IH40000	TRIAL HEAD D. 40 SHORT
0101213	APTA STEM W./CEM. TI=HA W/COLLAR TG. 3 L	IH40100	TRIAL HEAD D. 40 MEDIUM
0101214	APTA STEM W./CEM. TI=HA W/COLLAR TG. 4 L	IH40200	TRIAL HEAD D. 40 LONG
0101215	APTA STEM W./CEM. TI=HA W/COLLAR TG. 5 L		
0101216	APTA STEM W./CEM. TI=HA W/COLLAR TG. 6 L		
0101217	APTA STEM W./CEM. TI=HA W/COLLAR TG. 7 L		
0101218	APTA STEM W./CEM. TI=HA W/COLLAR TG. 8 L		
0420110	NECK MODULA SC 0X	IC00000	CHISEL
0420210	NECK MODULA SC 0A	IC00200	STEM IMPACTOR
0420220	NECK MODULA SC 0Y	IC00400	STEM EXTRACTOR
0420310	NECK MODULA SC 0B	IC00300	UNIVERSAL HANDLE
0420320	NECK MODULA SC 0C	IC00500	HEAD PUSHER
0420330	NECK MODULA SC 0Z	IC02200	ADDITIONAL EXTRACTOR
0429110	NECK MODULA SC 9X	IC00700	TOMMY BAR
0429120	NECK MODULA SC9AA	IC02400	NECKS IMPACTOR
0429130	NECK MODULA SC 9BB		
0429210	NECK MODULA SC 9A	IM00100	BLUE TRIAL NECK WHITE CAP 0B LONG
0429220	NECK MODULA SC 9Y	IM00200	BLUE TRIAL NECK GREY CAP 0C LONG
0429230	NECK MODULA SC 9CC	IM00300	BLUE TRIAL NECK BLACK CAP 0Z LONG
0429310	NECK MODULA SC9B	IM00400	RED TRIAL NECK WHITE CAP 0A MEDIUM
0429320	NECK MODULA SC 9C	IM00500	RED TRIAL NECK GREY CAP 0Y MEDIUM
0429330	NECK MODULA SC 9Z	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 9 ^o 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
		IM01200	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
0540321	HEAD METAL/METAL D. 32 SHORT		
0540322	HEAD METAL/METAL D. 32 MEDIUM		
0540323	HEAD METAL/METAL D. 32 LONG		
0540361	HEAD METAL/METAL D. 36 SHORT		
0540362	HEAD METAL/METAL D. 36 MEDIUM		

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Via Guelfa, 9
Tel. +39 051 533266
Fax +39 051 538772
40138 Bologna (ITALY)

SEDE LEGALE



Via Ciro Menotti, 11/D
Tel. +39 02 73951262
Fax +39 02 70005554
20129 MILANO (ITALY)

FILIALE



Via Pacinotti, 4/B
Tel. +39 045 8230327
Fax +39 045 8230660
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