



Surgical Technique

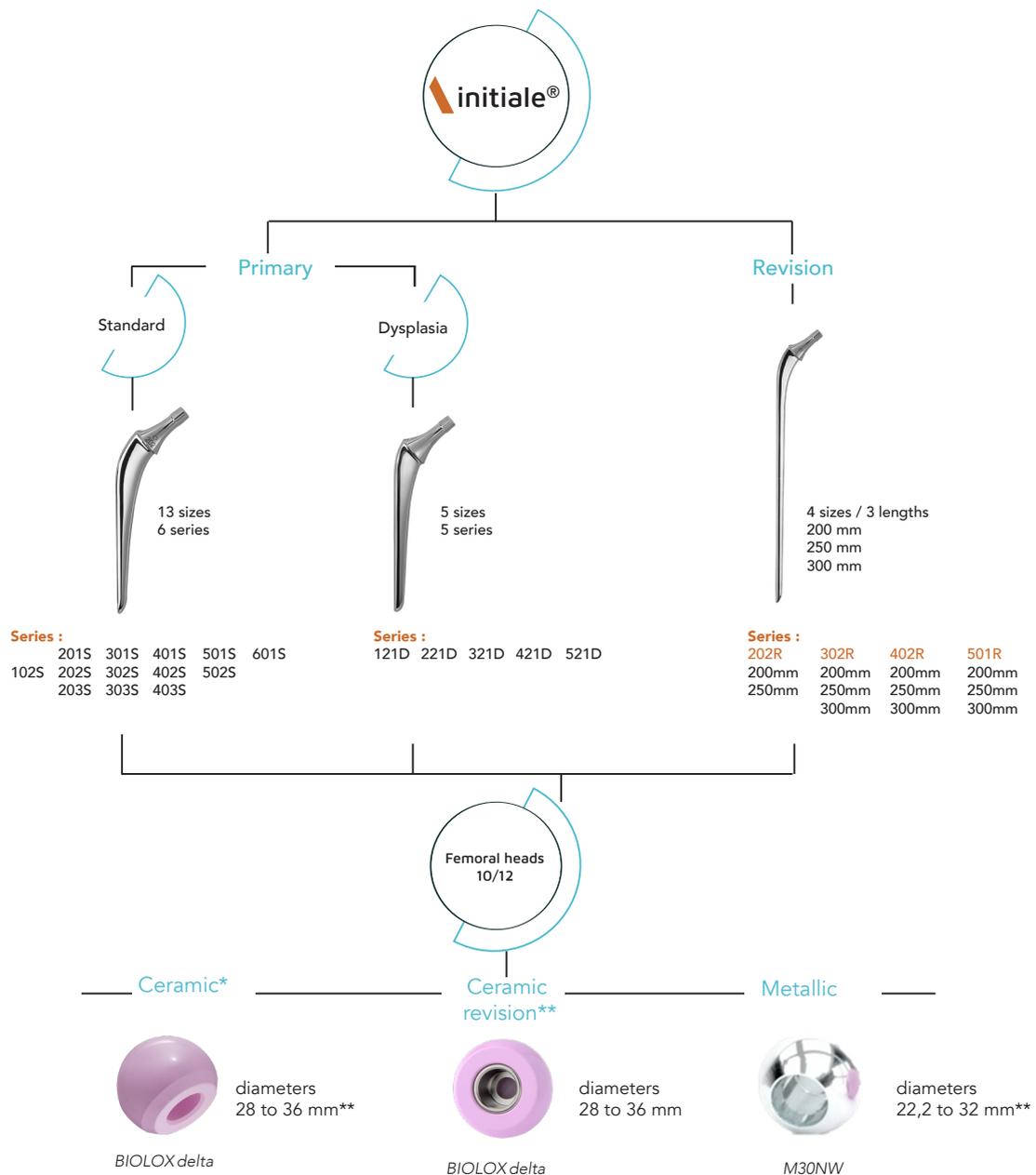


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Concept and Range



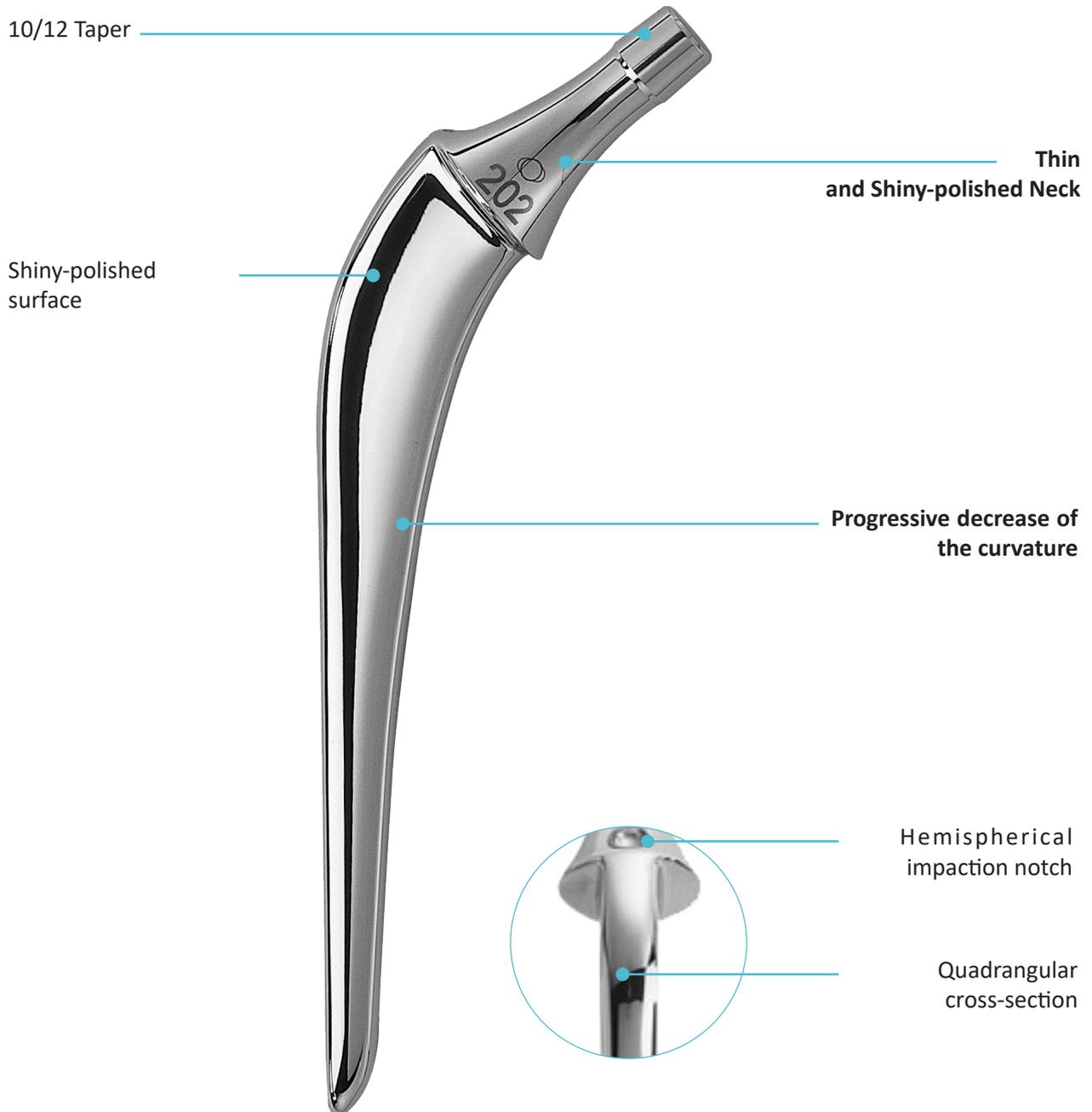
* Compatibility claimed for primary stems only

** Clinical compatibility not claimed for ceramic revision heads and diameters over 28mm

Concept and Range

Technical Features

INITIALE® straight femoral stems are intended for use with cement. Neck-shaft angle evolves with size. Intramedullary shape is defined by a progressive decrease of the curve in the frontal plane. **Cross-section of the stem is quadrangular.**

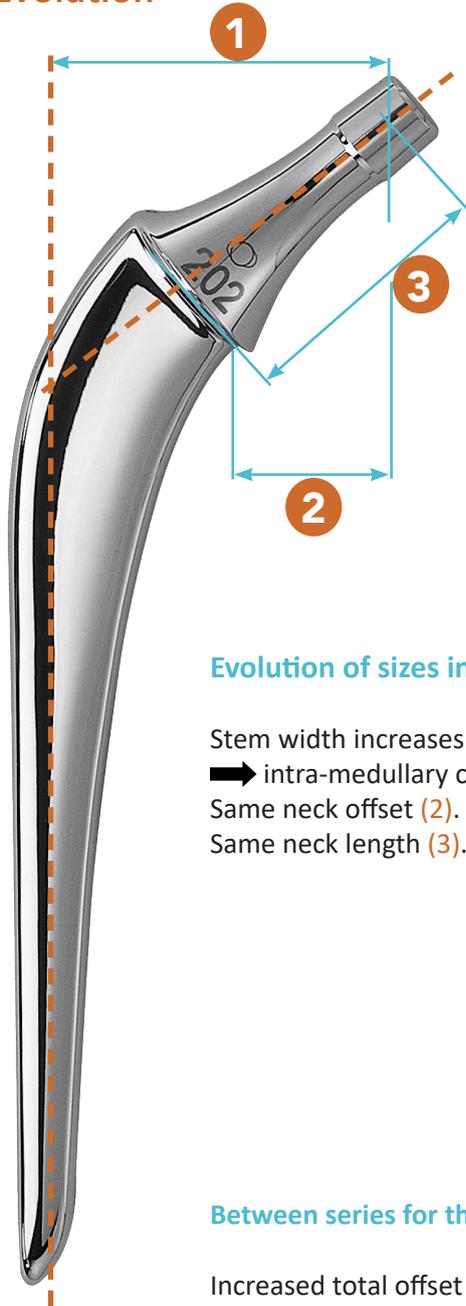


Material: Stainless Steel (M30NW)



Concept and Range

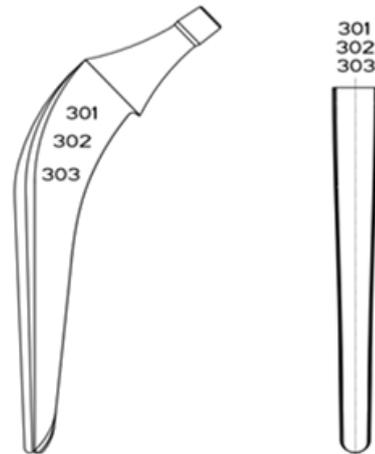
Evolution



- 1** Total Offset
- 2** Neck Offset
- 3** Neck Length

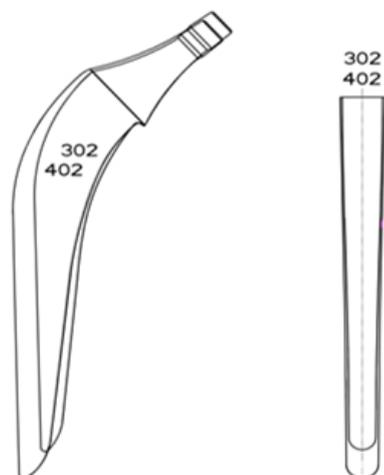
Evolution of sizes in the same series:

Stem width increases
 ──> intra-medullary congruency (1).
 Same neck offset (2).
 Same neck length (3).



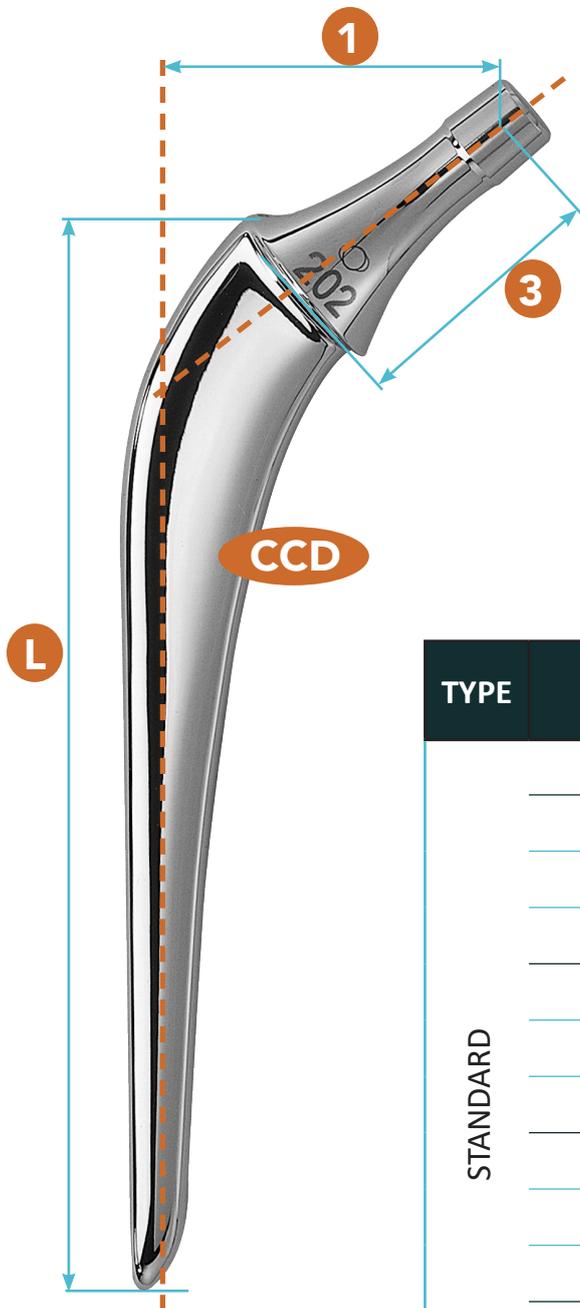
Between series for the same size:

Increased total offset (1).
 Increased neck offset (2).
 Increased neck length (3).



Concept and Range

Evolution



302 S

300 identifies the series

2 identifies the stem size number into the series

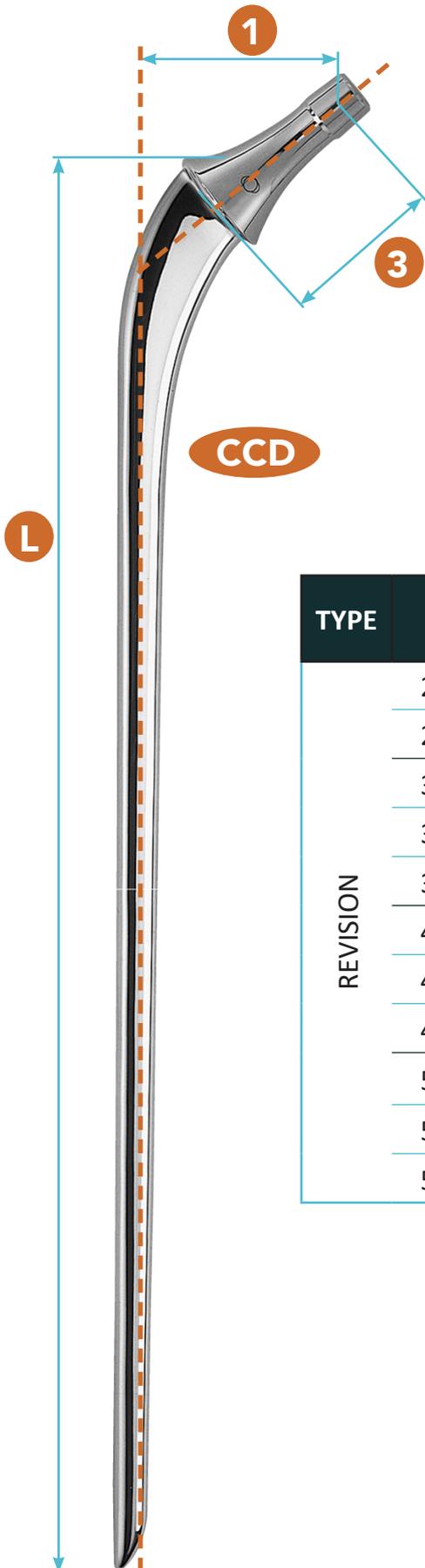
S = Standard
D = Dysplasia
R = Revision

TYPE	SIZE	CCD (Neck-shaft Angle)	1	L	3
STANDARD	102 S	129,3°	37	120	28
	201 S	129,3°	41		
	202 S	128,7°	42		
	203 S	128,1°	44	135	32
	301 S	130°	47		
	302 S	128,8°	49		
	303 S	128,1°	52	140	36
	401 S	130°	55		
	402 S	128,8°	56		
	403 S	127,3°	60	150	40
	501 S	130°	53		
	502 S	129°	56		
601 S	130°	58	165	55	
DYSPLASIA	121 D	130°	30	120	24
	221 D		35	130	32
	321 D		38	140	36
	421 D		41	150	40
	521 D		46	160	47



Concept and Range

Evolution

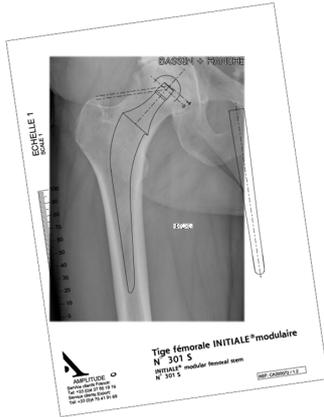


TYPE	SIZE	CCD (Neck-shaft Angle)	1	L	3
REVISION	202-200	129°	42	200	32
	202-250			250	
	302-200			200	
	302-250		49	250	36
	302-300		300		
	402-200		200		
	402-250	130°	56	250	40
	402-300			300	
	501-200			200	
	501-250	130°	53	250	47
	501-300			300	

Surgical technique overview

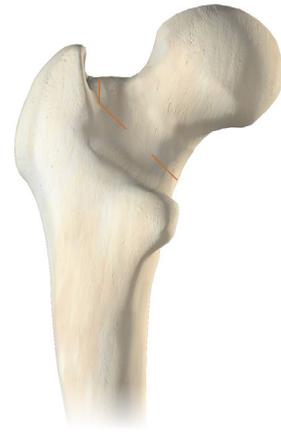
1

Pre-operative Planning



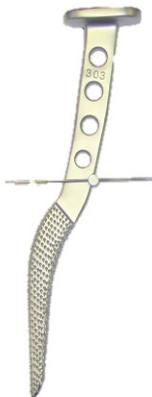
2

Femoral Neck Cut



3

Femoral Canal Preparation



4

Trials on Trial Stem



Surgical technique overview

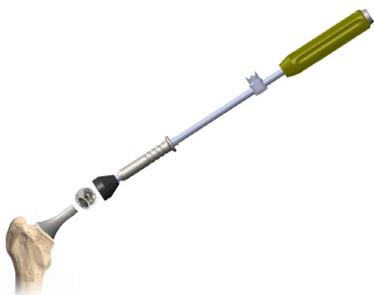
5
Final Stem Insertion
- Cement Restrictor



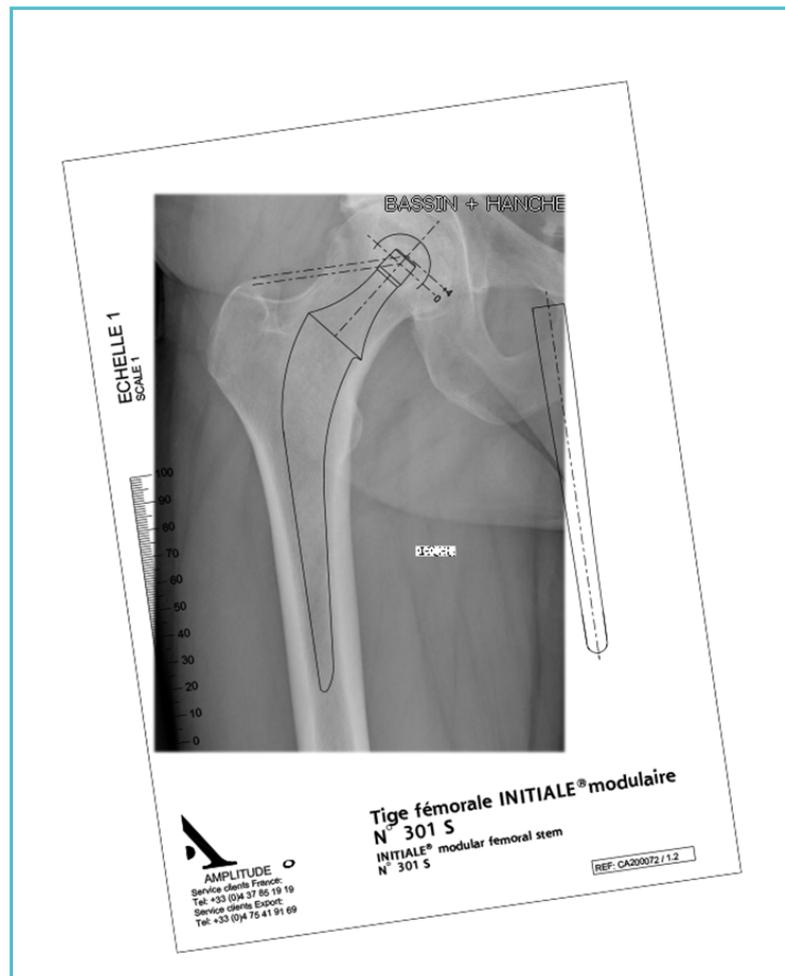
6
Final Stem Insertion



7
Final Head Impaction



1 Pre-operative Planning



Pre-operative planning is an important step to determine the implant size most adapted to restore the patient's anatomy. It must take into account anatomical and quality factors (bone quality, bone density, patient's morphology).

INITIALIA® femoral stem features several offset options and different angles (see pages 8 & 9), and the range is comprised of standard, dysplasia and revision versions.

- It is advised to choose an implant size allowing optimal fill of the femoral canal, leaving an even cement mantle around the stem.
- Stem choice and neck resection level must bring the best leg length and offset restoration possible. Neck resection level must be assessed closely.

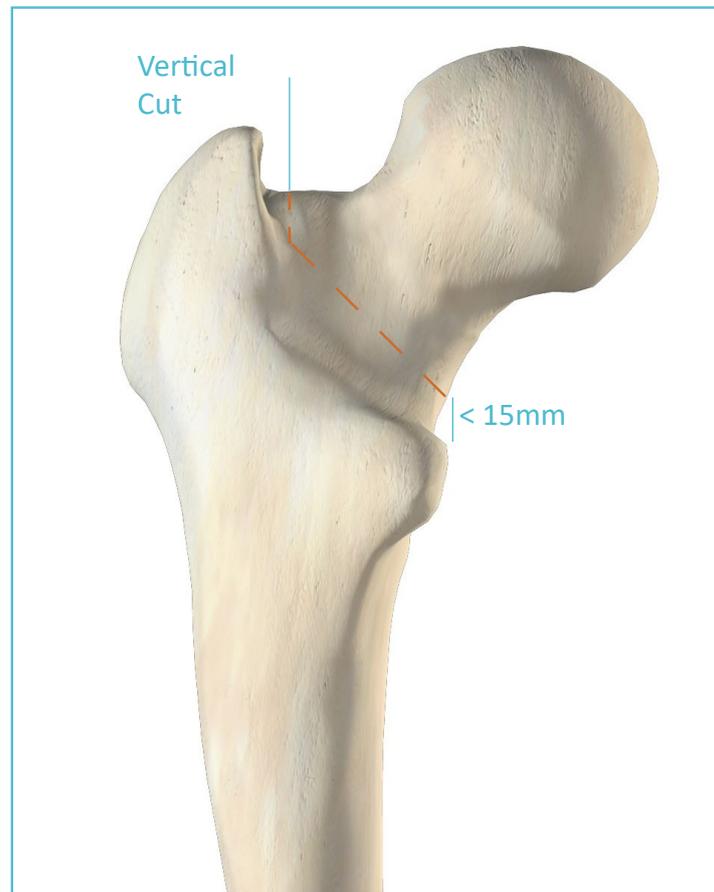
REMINDER

This surgical technique is intended for proper use of the instrumentation set. The surgical approach and the operating technique are entirely under the surgeon's responsibility.

NOTE

Templates are provided at 115% scale. Other magnifications and digital templates are available on request.

2 Femoral Neck Cut



Neck resection level, defined by templating, is reproduced based on anatomical landmarks (greater trochanter, lesser trochanter, trochanteric fossa).

As the stem features a collar, the cut should be oriented in the sagittal plane in order to achieve the desired anteversion.

Medullary canal broaching can be performed before or after acetabular preparation.

Neck resection can be done before or after femoral head dislocation. Start by hollowing the femoral neck from its trabecular bone (some amount can be kept in order to be used as cement distal plug if necessary). Make sure to carefully prepare the supero-external part of the neck to avoid any varus positioning of the stem.

3 Femoral Canal Preparation



Femoral canal opening:

Femoral canal is prepared with the smallest broach, then with increasing size of broaches.

Metaphyseal preparation:

Broach successively until templated size has been reached. Broaches are slightly oversized and feature teeth in order to have enough clearance for bone cement.

To check leg length, insert the blunt K-wire in the broach handle. This allows to check the horizontal projection of a medium neck femoral head against the greater trochanter per-operatively. This will ensure it matches the height defined during planning.

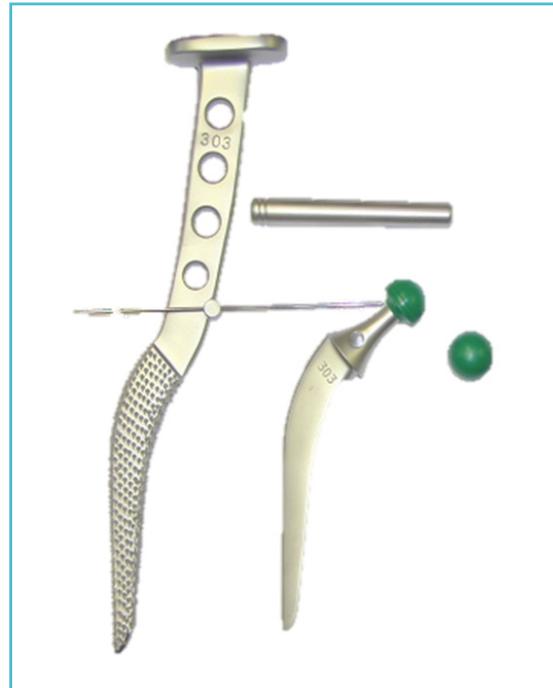
NOTE

For INITIALE® Revision, ream the diaphyseal canal over at least the length of the final stem

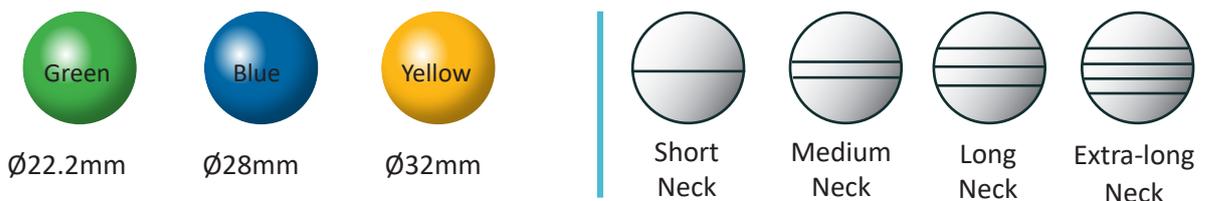
NOTE

INITIALE® broaches range offers several broach designs adapted to the surgical approach (anterior, posterior).

4 Trials on Trial Stem



Select the trial stem of the same size as the last broach. Place the trial stem in the femur, with a trial head of the desired size and length.



Reduce the joint using the femoral head impaction, assembled on the universal handle. Perform stability and range of motion trials, and check leg length to validate the extramedullary settings. Check rotational stability of the trial stem, collar matching with neck resection, and anteversion with the broach handle extraction shaft.

Remove the trial head and the trial stem from the femur.

NOTE
Perform trials until reaching anteversion and neck length that offers the best stability and range of motion.

NOTE
Blunt K-wire placed in the broach handle allows visual assesment of the medium neck head center to reproduce templating.

5 Final Stem Insertion

Cement Restrictor Insertion



Wash and dry the intramedullar femoral cavity. Femoral canal obturation should be performed according to the surgeon's habits. The AMPLITUDE range offers the TEKSTOP®, absorbable restrictor, a one-size non-absorbable UHMWPE restrictor, and a non-resorbable solid fin plug.

Introduce the cement restrictor depending on the model used :

TEKSTOP® :

Based on femoral canal preparation, determine in the instrumentation the adequate trial «olive» diameter and assemble it on the handle by threading it completely ①.

Tighten the holding screw on the body of the inserter ②.

Compare the length with the validated broach by using a landmark that can be used to determine adequate insertion depth.

Insert in the femoral canal until determined depth is reached to assess the diameter. Repeat trials until diameter has been validated. Remove the trial "olive" by unthreading it.

Choose the TEKSTOP® restrictor of the same size as the validated trial "olive", assemble it on the inserter, and insert it in the femoral canal.

Unthread the holding screw ③ and pull the handle to leave the TEKSTOP® restrictor in place ④.

Non-absorbable cement restrictor:

Assemble the non-absorbable restrictor on the introducer.

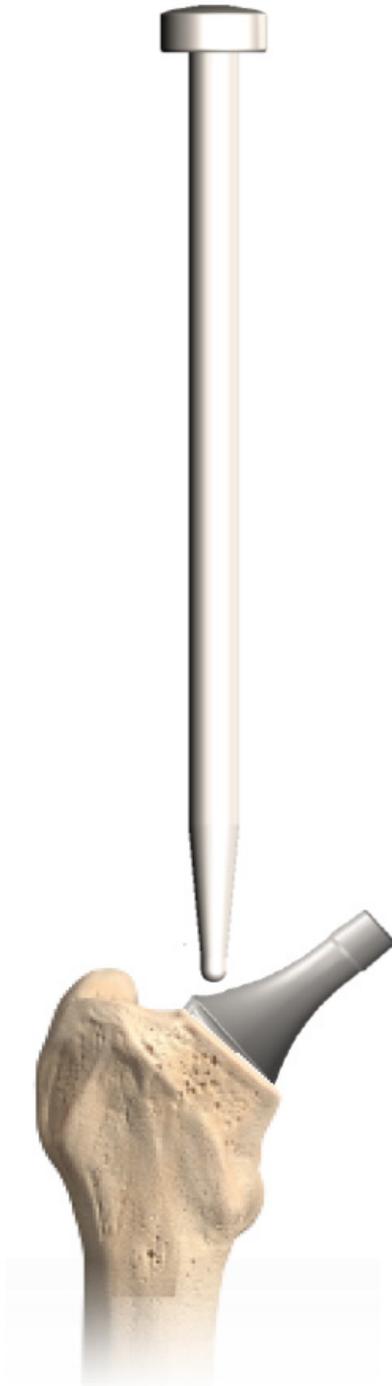
The graduation on the inserter indicates insertion depth. Compare with the validated broach by using a landmark that can be used to determine adequate insertion depth. Add 1cm to ensure positioning well below the stem.

Insert in the femoral canal until determined depth is reached.

Remove the inserter to leave the restrictor in place.

5 Final Stem Insertion

Final Stem Insertion



Following probable muscular or bone reinsertion wires, the medullary canal is washed and dried. Cement is introduced using a bone syringe in the canal. Obturation of the canal is made based on the surgeon's habits.

Prosthesis is inserted in the femur and maintained in place until complete cement polymerization thanks to the stem impactor.

It is then possible to perform new trials with trial heads on the stem if necessary (to validate neck length and articular stability).

NOTE

Follow instructions for use of the cement being used.

6 Final Head Impaction



Select the final head corresponding to the one validated previously.

Before placing the ceramic head on the femoral stem:

- Dry the stem taper
- Carefully inspect the stem taper and the head taper, and remove any foreign material.

Impaction of a metallic or ceramic head:

Manually place the head on the stem taper using a slight turning motion while pushing along the taper axis, until it firmly wedges. Secure the head on the stem taper using the head impactor: tap the impactor with a light hammer blow in the taper axis.

Reduce the joint.

Impaction of a ceramic head:

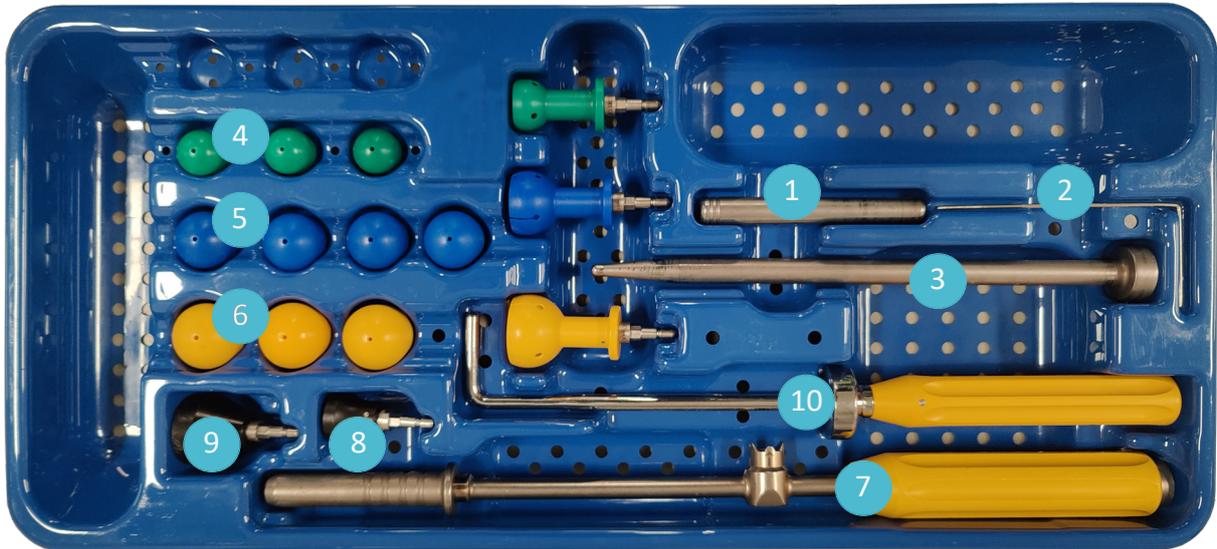
Manually assemble the sleeve into the head on the table, until resistance is felt. Manually place the head on the stem taper using a slight turning motion while pushing along the taper axis, until it firmly wedges. Secure it using the head impactor with a light hammer blow in the taper axis.

Reduce the joint.



Instrumentation

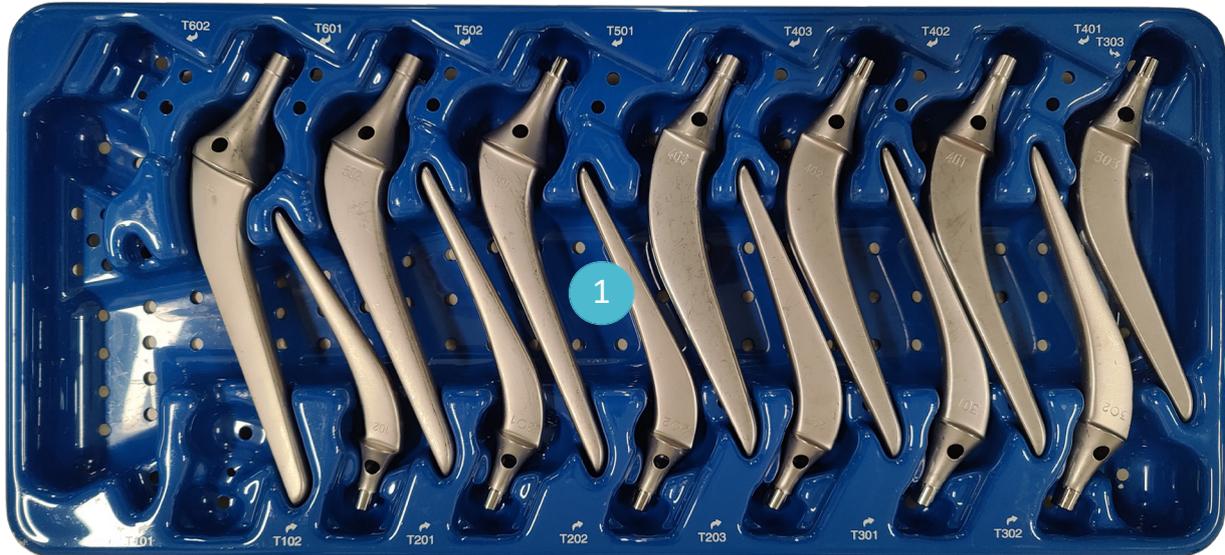
Standard Trial Set



Rep	Description	Reference	Qty
1	Broach handle extraction shaft	2-0104700	1
2	Alignment Pin \varnothing 2 A/P	2-0114000	1
3	Femoral stem impactor	2-0104800	1
4	Trial head 10/12 \varnothing 22.2 Short, Medium, Long Neck	2-0100405 to 07	1
5	Trial head 10/12 \varnothing 28 Short, Medium, Long, Extra-long Neck	2-0100401 to 04	1
6	Trial head 10/12 \varnothing 32 Short, Medium, Long Neck	2-0100408 to 10	1
7	Universal Handle - Conventional/navigated	2-0117600	1
8	Impactor for \varnothing 22.2 Heads	2-0101400	1
9	Impactor for \varnothing 28 and \varnothing 32 Heads	2-0114200	1
10	Trial stem extractor	2-0106700	1

Instrumentation

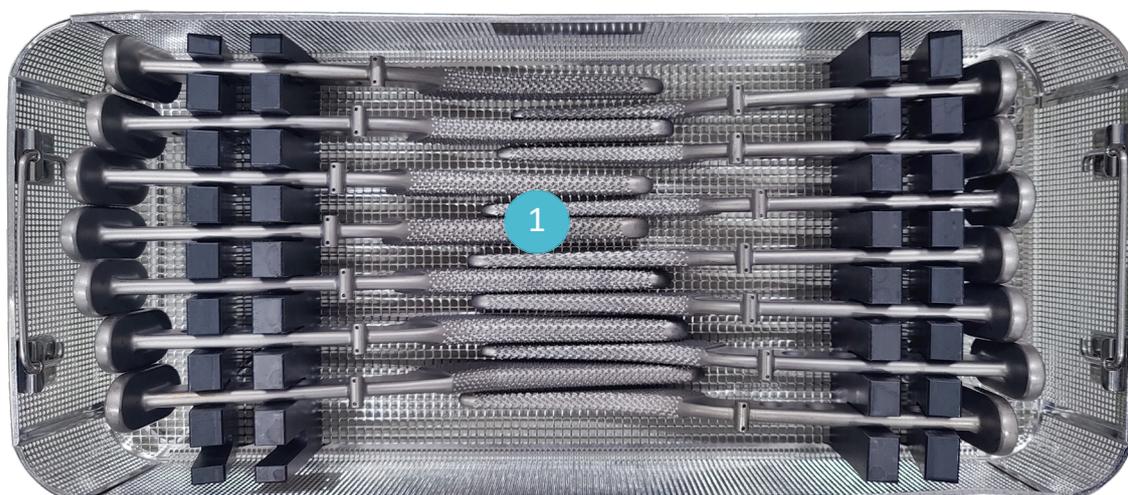
Standard Trial Set



Rep	Description	Reference	Qty
1	Trial INITIALE femoral stem N° 102S	2-0180102	1
1	Trial INITIALE femoral stem N° 201S	2-0180201	1
1	Trial INITIALE femoral stem N° 202S	2-0180202	1
1	Trial INITIALE femoral stem N° 203S	2-0180203	1
1	Trial INITIALE femoral stem N° 301S	2-0180301	1
1	Trial INITIALE femoral stem N° 302S	2-0180302	1
1	Trial INITIALE femoral stem N° 303S	2-0180303	1
1	Trial INITIALE femoral stem N° 401S	2-0180401	1
1	Trial INITIALE femoral stem N° 402S	2-0180402	1
1	Trial INITIALE femoral stem N° 403S	2-0180403	1
1	Trial INITIALE femoral stem N° 501S	2-0180501	1
1	Trial INITIALE femoral stem N° 502S	2-0180502	1
1	Trial INITIALE femoral stem N° 601S	2-0180601	1

Instrumentation

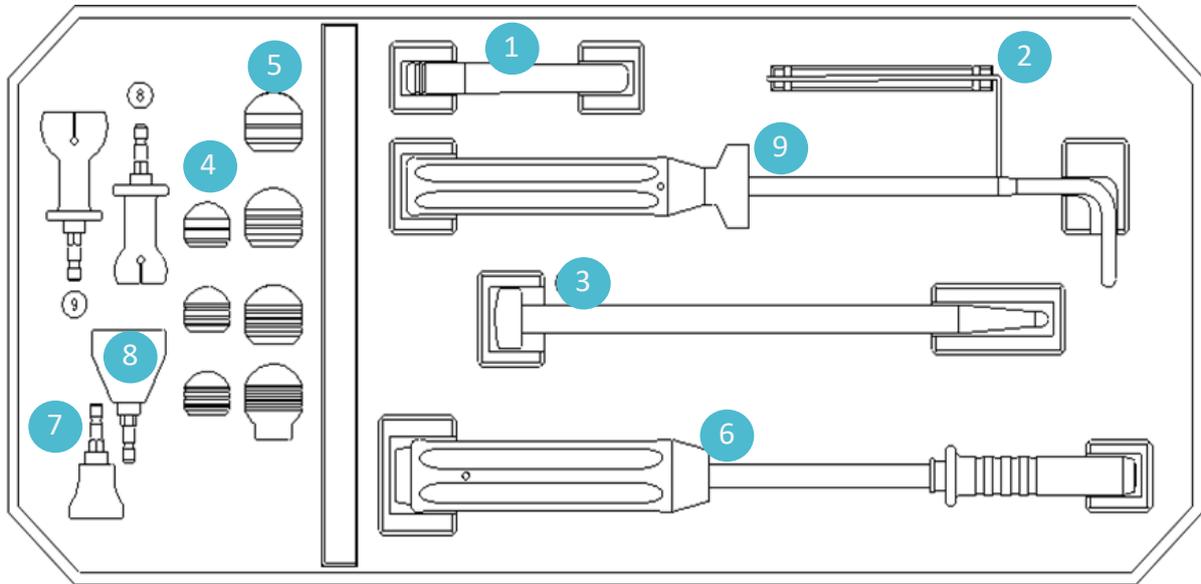
Femoral Preparation Set



Rep	Description	Reference	Qty
1	INITIALE femoral broach N°101S	2-0170101	1
1	INITIALE femoral broach N°102S	2-0170102	1
1	INITIALE femoral broach N°201S	2-0170201	1
1	INITIALE femoral broach N°202S	2-0170202	1
1	INITIALE femoral broach N°203S	2-0170203	1
1	INITIALE femoral broach N°301S	2-0170301	1
1	INITIALE femoral broach N°302S	2-0170302	1
1	INITIALE femoral broach N°303S	2-0170303	1
1	INITIALE femoral broach N°401S	2-0170401	1
1	INITIALE femoral broach N°402S	2-0170402	1
1	INITIALE femoral broach N°403S	2-0170403	1
1	INITIALE femoral broach N°501S	2-0170501	1
1	INITIALE femoral broach N°502S	2-0170502	1
1	INITIALE femoral broach N°601S	2-0170601	1

Instrumentation

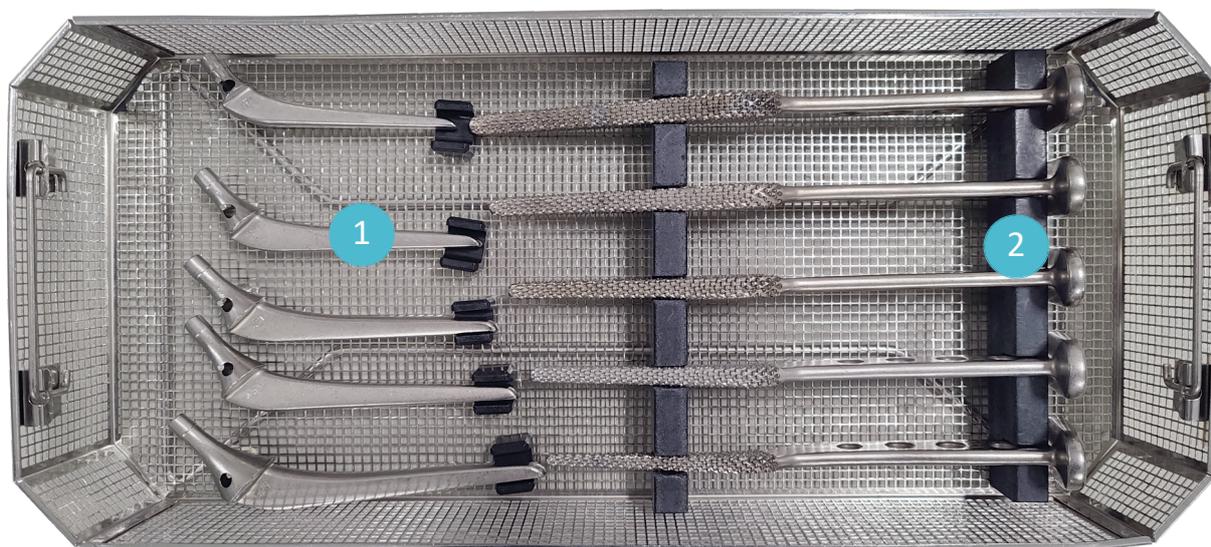
Dysplasia Trial Set



Rep	Description	Reference	Qty
1	Broach handle extraction shaft	2-0104700	1
2	Alignment Pin \varnothing 2 A/P	2-0114000	1
3	Femoral stem impactor	2-0104800	1
4	Trial head 10/12 \varnothing 22.2 Short, Medium, Long Neck	2-0100405 to 07	1
5	Trial head 10/12 \varnothing 28 Short, Medium, Long, Extra-long Neck	2-0100401 to 04	1
6	Universal Handle	2-0101000	1
7	Impactor for \varnothing 22.2 Heads	2-0101400	1
8	Impactor for \varnothing 28 and \varnothing 32 Heads	2-0114200	1
9	Trial stem extractor	2-0106700	1

Instrumentation

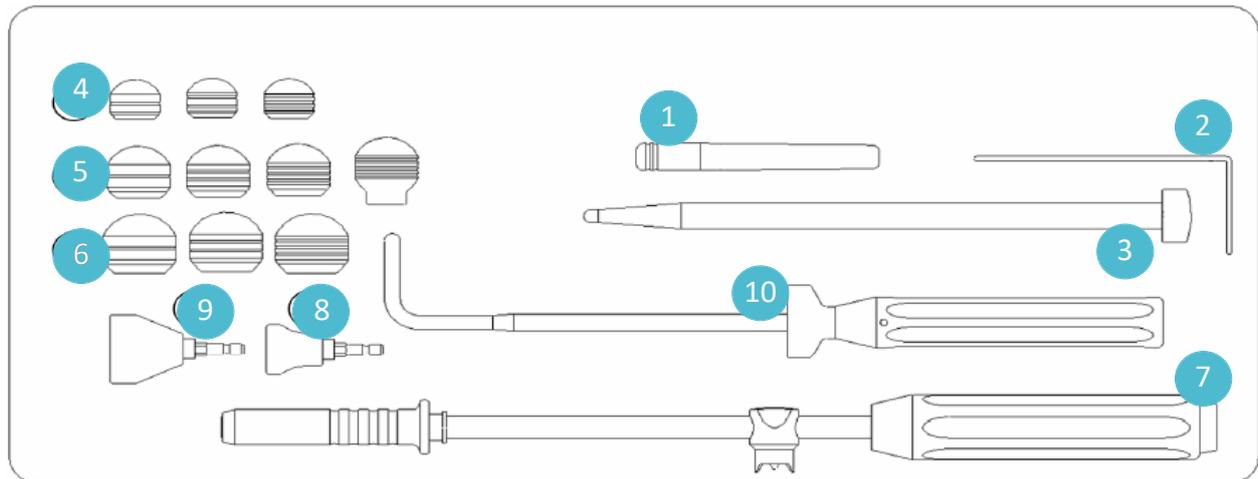
Dysplasia Trial Set



Rep	Description	Reference	Qty
1	INITIALE dysplasia femoral broach N° 121 D	2-0140121	1
1	INITIALE dysplasia femoral broach N° 221 D	2-0140221	1
1	INITIALE dysplasia femoral broach N° 321 D	2-0140321	1
1	INITIALE dysplasia femoral broach N° 421 D	2-0140421	1
1	INITIALE dysplasia femoral broach N° 521 D	2-0140521	1
2	Trial INITIALE Dysplasia femoral stem N° 121 D	2-0150121	1
2	Trial INITIALE Dysplasia femoral stem N° 221 D	2-0150221	1
2	Trial INITIALE Dysplasia femoral stem N° 321 D	2-0150321	1
2	Trial INITIALE Dysplasia femoral stem N° 421 D	2-0150421	1
2	Trial INITIALE Dysplasia femoral stem N° 521 D	2-0150521	1

Instrumentation

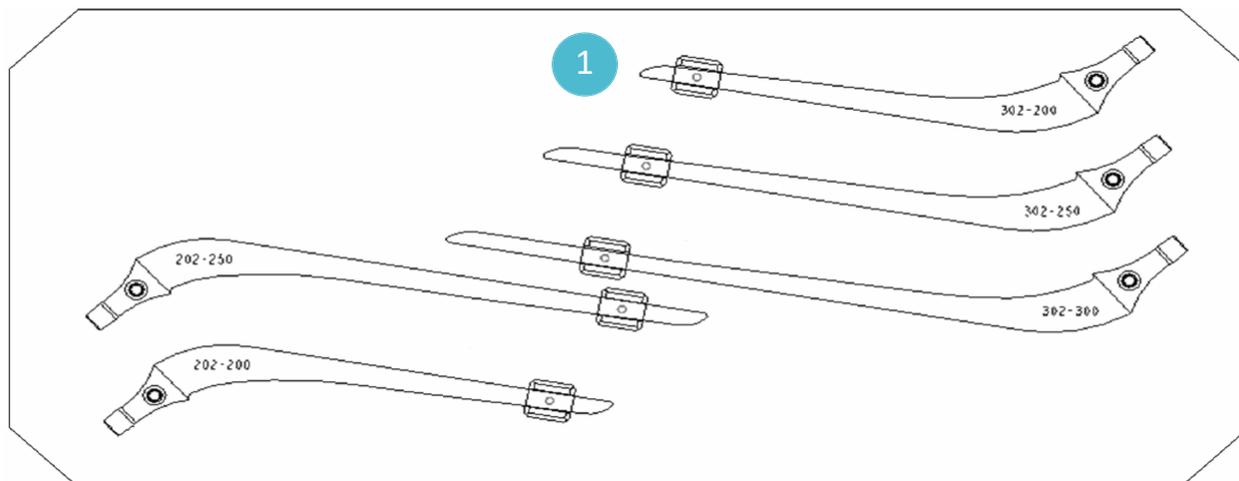
Revision Trial Set



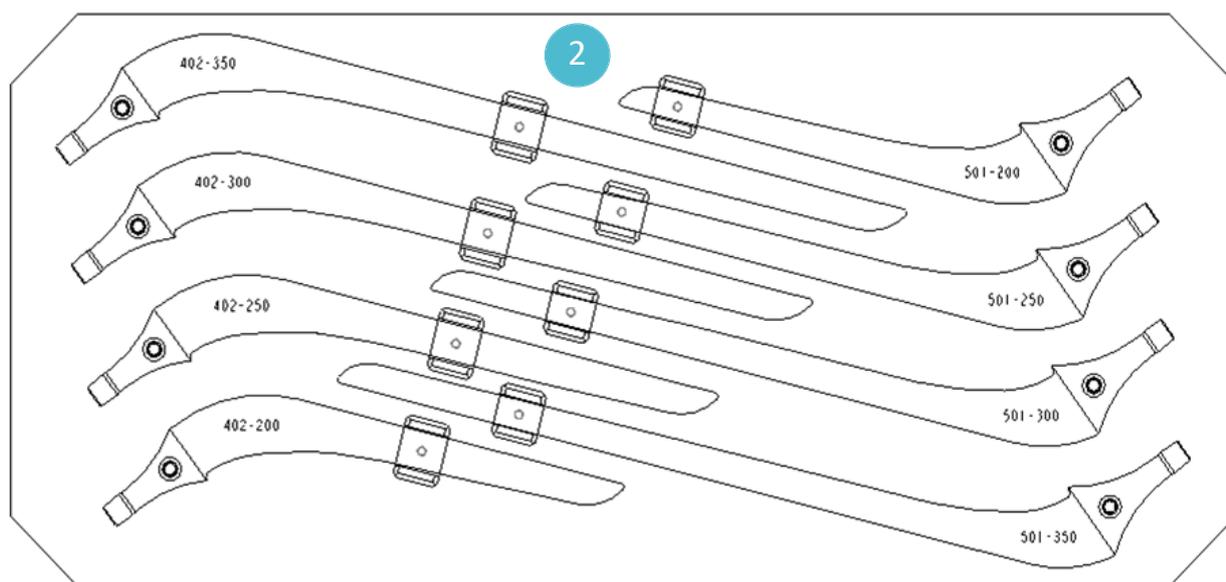
Rep	Description	Reference	Qty
1	Broach handle extraction shaft	2-0104700	1
2	Alignment Pin \varnothing 2 A/P	2-0114000	1
3	Femoral stem impactor	2-0104800	1
4	Trial head 10/12 \varnothing 22.2 Short, Medium, Long Neck	2-0100405 to 07	1
5	Trial head 10/12 \varnothing 28 Short, Medium, Long, Extra-long Neck	2-0100401 to 04	1
6	Trial head 10/12 \varnothing 32 Short, Medium, Long Neck	2-0100408 to 10	1
7	Universal Handle - Conventional/navigated	2-0117600	1
8	Impactor for \varnothing 22.2 Heads	2-0101400	1
9	Impactor for \varnothing 28 and \varnothing 32 Heads	2-0114200	1
10	Trial stem extractor	2-0106700	1

Instrumentation

Revision Trial Set



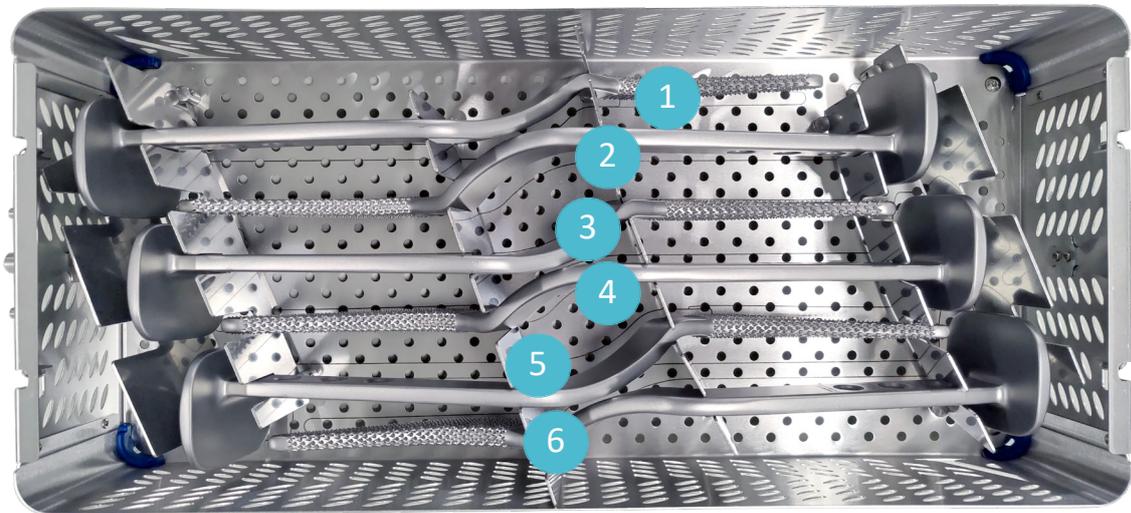
Rep	Description	Reference	Qty
1	Trial INITIALIA Revision femoral stem N° 202-200mm	2-0120220	1
1	Trial INITIALIA Revision femoral stem N° 202-250mm	2-0120225	1
1	Trial INITIALIA Revision femoral stem N° 302-200mm	2-0120320	1
1	Trial INITIALIA Revision femoral stem N° 302-250mm	2-0120325	1
1	Trial INITIALIA Revision femoral stem N° 302-300mm	2-0120330	1



Rep	Description	Reference	Qty
2	Trial INITIALIA Revision femoral stem N° 402-200mm	2-0120420	1
2	Trial INITIALIA Revision femoral stem N° 402-250mm	2-0120425	1
2	Trial INITIALIA Revision femoral stem N° 402-300mm	2-0120430	1
2	Trial INITIALIA Revision femoral stem N° 501-200mm	2-0120520	1
2	Trial INITIALIA Revision femoral stem N° 501-250mm	2-0120525	1
2	Trial INITIALIA Revision femoral stem N° 501-300mm	2-0120530	1

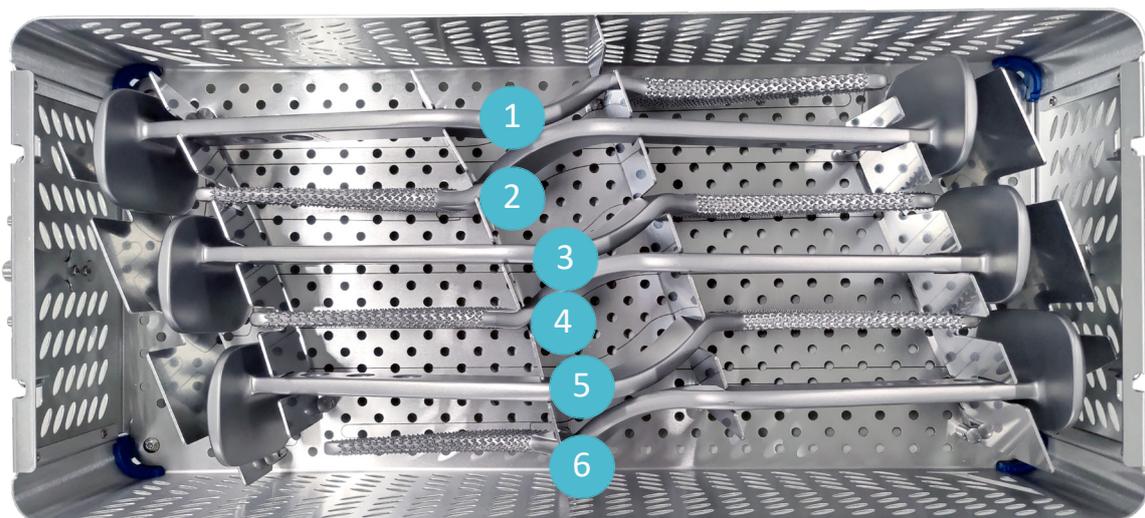
Instrumentation

Dual Offset Broaches Tray - Left



Rep	Description	Reference	Qty
1	INITIALE Broach - Dual Offset - Left - Size 102S	2-1100112	1
2	INITIALE Broach - Dual Offset - Left - Size 201S	2-1100121	1
3	INITIALE Broach - Dual Offset - Left - Size 202S	2-1100122	1
4	INITIALE Broach - Dual Offset - Left - Size 203S	2-1100123	1
5	INITIALE Broach - Dual Offset - Left - Size 301S	2-1100131	1
6	INITIALE Broach - Dual Offset - Left - Size 302S	2-1100132	1

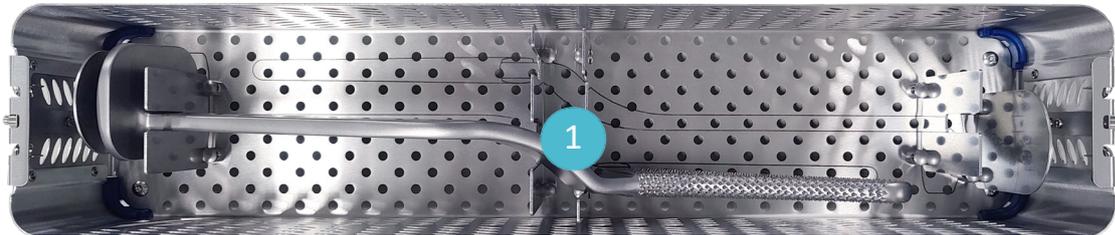
Dual Offset Broaches Tray - Left



Rep	Description	Reference	Qty
1	INITIALE Broach - Dual Offset - Left - Size 303S	2-1100133	1
2	INITIALE Broach - Dual Offset - Left - Size 401S	2-1100141	1
3	INITIALE Broach - Dual Offset - Left - Size 402S	2-1100142	1
4	INITIALE Broach - Dual Offset - Left - Size 403S	2-1100143	1
5	INITIALE Broach - Dual Offset - Left - Size 501S	2-1100151	1
6	INITIALE Broach - Dual Offset - Left - Size 502S	2-1100152	1

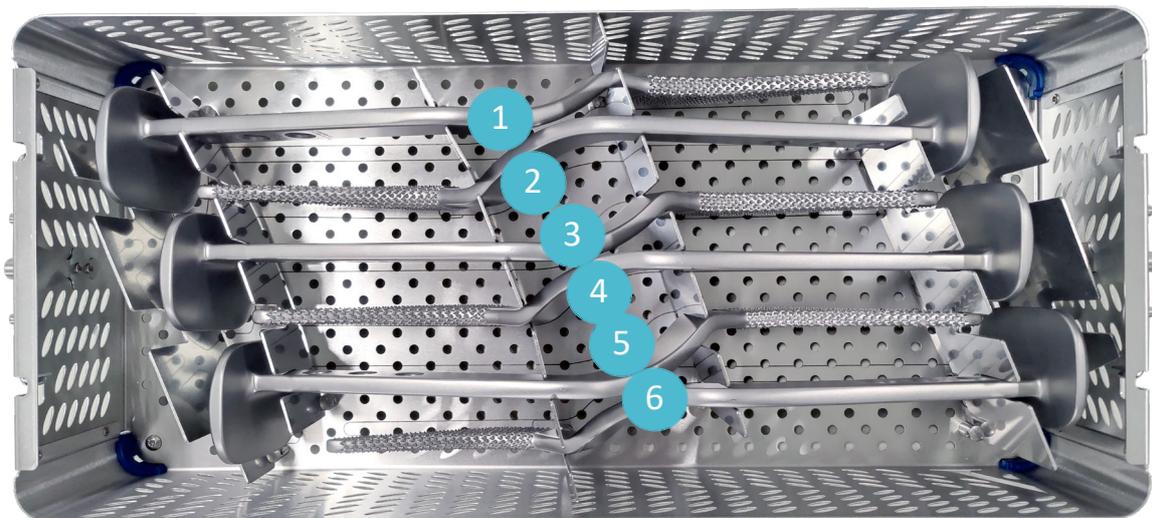
Instrumentation

Dual Offset Broaches Tray - Left



Rep	Description	Reference	Qty
1	INITIALE Broach - Dual Offset - Left - Size 601S	2-1100161	1

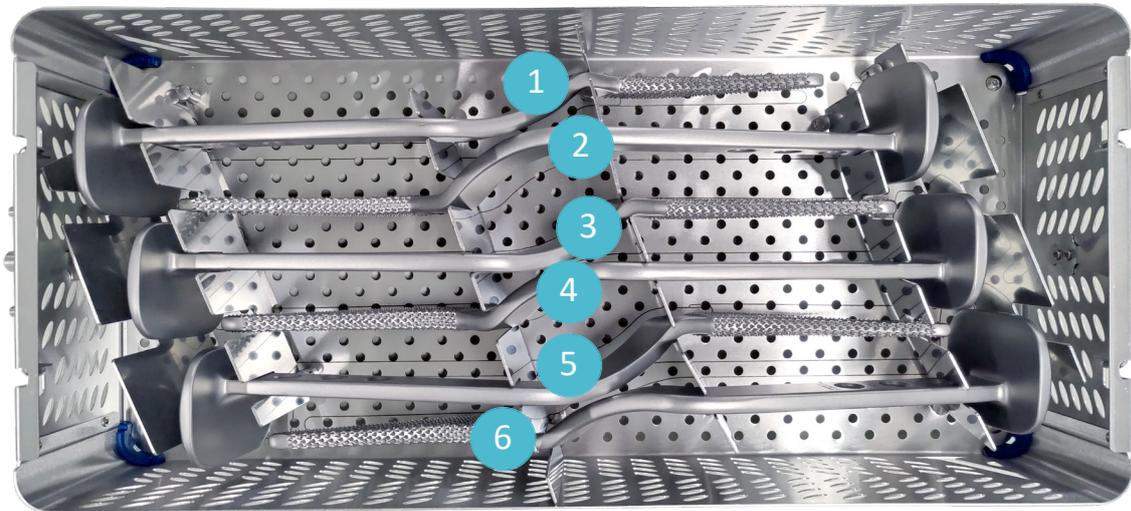
Dual Offset Broaches Tray - Right



Rep	Description	Reference	Qty
1	INITIALE Broach - Dual Offset - Right - Size 102S	2-1100212	1
2	INITIALE Broach - Dual Offset - Right - Size 201S	2-1100221	1
3	INITIALE Broach - Dual Offset - Right - Size 202S	2-1100222	1
4	INITIALE Broach - Dual Offset - Right - Size 203S	2-1100223	1
5	INITIALE Broach - Dual Offset - Right - Size 301S	2-1100231	1
6	INITIALE Broach - Dual Offset - Right - Size 302S	2-1100232	1

Instrumentation

Dual Offset Broaches Tray - Right



Rep	Description	Reference	Qty
1	INITIALE Broach - Dual Offset - Right - Size 303S	2-1100233	1
2	INITIALE Broach - Dual Offset - Right - Size 401S	2-1100241	1
3	INITIALE Broach - Dual Offset - Right - Size 402S	2-1100242	1
4	INITIALE Broach - Dual Offset - Right - Size 403S	2-1100243	1
5	INITIALE Broach - Dual Offset - Right - Size 501S	2-1100251	1
6	INITIALE Broach - Dual Offset - Right - Size 502S	2-1100252	1

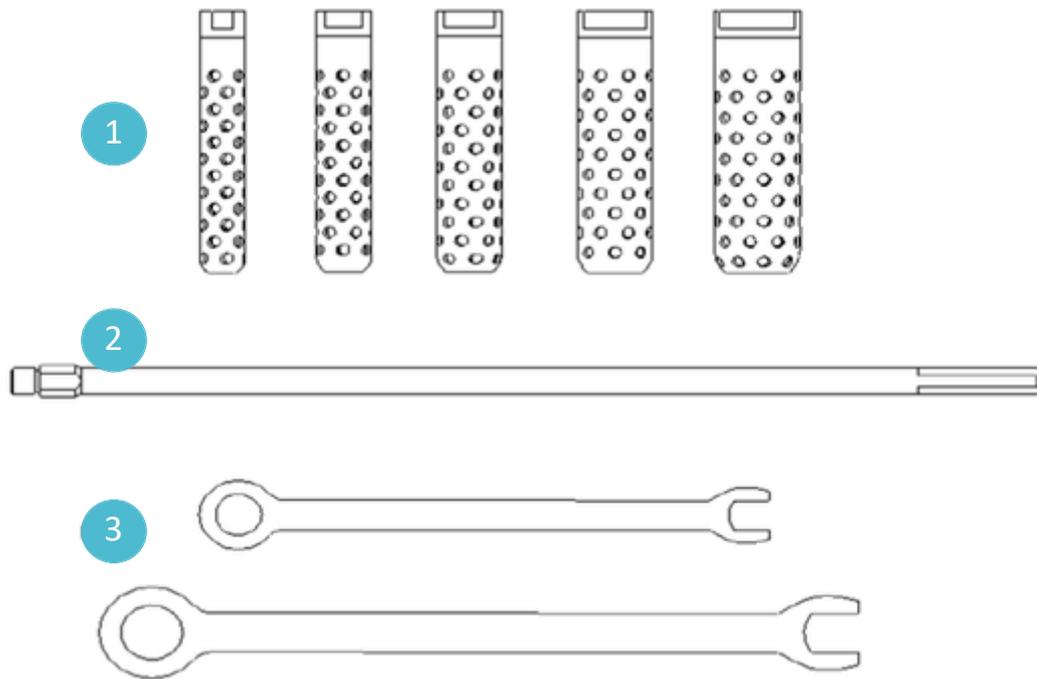
Dual Offset Broaches Tray - Right



Rep	Description	Reference	Qty
1	INITIALE Broach - Dual Offset - Right - Size 601S	2-1100261	1

Instrumentation

Optional: Cylindrical Reamers



Rep	Description	Reference	Qty
1	Cylindrical reamer $\varnothing 10$	2-0109110	1
1	Cylindrical reamer $\varnothing 12$	2-0109112	1
1	Cylindrical reamer $\varnothing 14$	2-0109114	1
1	Cylindrical reamer $\varnothing 16$	2-0109116	1
1	Cylindrical reamer $\varnothing 18$	2-0109118	1
2	Cylindrical reamer handle	2-0109000	1
3	Inox flat wrench 6 mm	K1254	1
3	Inox flat wrench 8 mm	K1255	1





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