MODULUS

FEMORAL STEM

SURGICAL TECHNIQUE

Lima Corporate
Orthopaedic motion

MODULUS FEMORAL STEM SURGICAL TECHNIQUE

Index

Limacorporate spa, as manufacturer of prosthetic devices, does not practice medicine. This surgical technique has been developed in consultation with an experienced surgeon team and provides the surgeon with general guidance when implanting the MODULUS stem. Proper surgical procedures and techniques are necessarily the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of the surgical technique used based on personal medical training, experience and clinical evaluation of each individual patient.

LEONARDO DA VINCI: Vitruvian Man. Study of the proportions of the human body (1490).

INDICATIONS

MODULUS is indicated for use in partial or total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with following conditions:

- non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis and hip dysplasia;
- rheumatoid arthritis;
- osteoarthritis after femoral heads fractures;
- correction of functional deformity;
- revision in cases of good remaining femoral bone stock.

Please follow the instructions for use enclosed in the product packaging.

CONTRAINDICATIONS

Absolute contraindications include:

- local or systemic infection;
- septicaemia;
- persistent acute or chronic osteomyelitis;
- confirmed nerve or muscle lesion compromising hip joint function.

Relative contraindications include:

- vascular or nerve diseases affecting the concerned limb;
- poor bone stock (for example due to osteoporosis) compromising the stability of the implant;
- metabolic disorders which may impair fixation and stability of the implant;
- any concomitant disease and dependence that might affect the implanted prosthesis;
- metal hypersensitivity to implant materials.

RISK FACTORS

The following risk factors may result in poor results with this prosthesis:

- overweight;
- strenuous physical activities (active sports, heavy physical work);
- fretting on modular junctions;
- incorrect implant positioning (e.g.:varus positioning);
- medical disabilities which can lead to an unnatural gait and loading of the hip joint;
- muscle deficiencies;
- multiple joint disabilities;
- refusal to modify postoperative physical activities;
- patient's history of infections or falls;
- systemic diseases and metabolic disorders;
- local or disseminated neoplastic diseases;
- drug therapies that adversely affect bone quality, healing, or resistance to infection;
- drug use or alcoholism;
- marked osteoporosis or osteomalacia;
- patient's resistance to disease generally weakened (HIV, tumour, infections);
- severe deformity leading to impaired anchorage or improper positioning of implants.

Indications and Contraindications

PRE-OPERATIVE PLANNING

Pre-operative planning, through radiographic templates in different formats, provides essential information regarding the type and size of components to be used and the correct combination of devices required based on the anatomy and on the specific conditions of each patient. Inadequate pre-operative planning can lead to improper selection of the implants and/or incorrect implant positioning.

Surgeon should carefully plan the surgery considering the following:

1. small sized stems (i.e. Taper A components, not available in US) are designed for patients with a small intramedullary canal and/or metaphyseal region of the femur. The reduced size (diameter) of these stems results in a corresponding reduction in the fatigue strength of the implant;
2. complications or failures of the total hip replacement may occur in heavy and highly active patients and high offset combinations.

The surgeon should perform a careful evaluation of the patient's clinical condition and level of physical activity before performing hip replacement.
Patients who are overweight and/or have high activity levels may not be candidates for hip replacement with modular stems.
Alternative devices, such as monoblock hip stems, should be used, when possible, in these patients.

COMBINATIONS ALLOWED/NOT ALLOWED

Allowed combination between femoral head and femoral necks:

- only the head sizes S, M and L can be coupled with femoral necks #L (125° and 135°);
- only the head sizes S, M, L and XL can be coupled with femoral necks #S (125° and 135°).

Use of femoral heads with greater neck lengths may result in failure of the hip stem (e.g.: breakage due to fatigue).

Allowed combination between Modulus stems and femoral necks:

- combine only "taper A" stems with "taper A" femoral necks;
- combine only "taper B" stems with "taper B" femoral necks;
- the use of B-LARGE necks, when available, is suggested for stems with a diameter greater than 20 mm.

STEM SIZES

MODULUS is comprised of 14 sizes distal components. Stems diameter increases by 1 mm per incrementing size.

Stems #13 - #15 are compatible with Taper A modular necks.
Stems #16 - #26 are compatible with taper B modular necks.

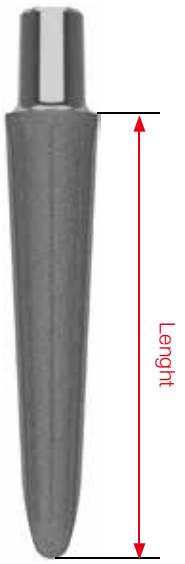
Suggested combinations:

- stems #16 - #20 are coupled with B modular necks;
- stems #21 - #26 are coupled with B-Large modular necks.

The standard version modular necks, short and long, has neck-shaft angle of 135°, while the lateralizing version has neck-shaft angle of 125° (+5 mm offset).

MODULUS STEMS

SIZE (Ø)	LENGTH	TAPER	MODULAR NECKS
13 mm	87 mm	A	A
14 mm	96 mm	A	A
15 mm	100 mm	A	A
16 mm	100 mm	B	B
17 mm	100 mm	B	B
18 mm	100 mm	B	B
19 mm	100 mm	B	B
20 mm	100 mm	B	B
21 mm	100 mm	B	B – Large
22 mm	100 mm	B	B – Large
23 mm	100 mm	B	B – Large
24 mm	100 mm	B	B – Large
25 mm	100 mm	B	B – Large
26 mm	100 mm	B	B – Large



MODULUS FEMORAL STEM SURGICAL TECHNIQUE

Stem Sizes

MODULUS NECKS

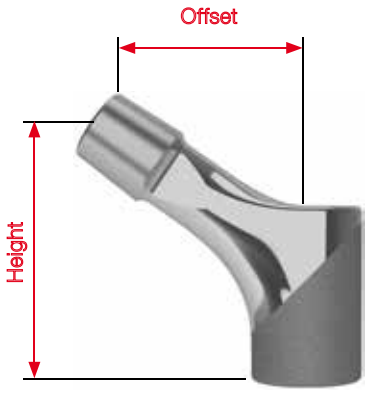
STANDARD – 135° :

- Taper A – with Head M (+0 mm)

SIZE	Ø	OFFSET	HEIGHT
S	16 mm	23 mm	41 mm
L	16 mm	31 mm	44 mm

- Taper B – with Head M (+0 mm)

SIZE	Ø	OFFSET	HEIGHT
S	19 mm	28 mm	42 mm
L	19 mm	36 mm	48 mm
Large S	23 mm	28 mm	42 mm
Large L	23 mm	36 mm	48 mm



CCD 135°

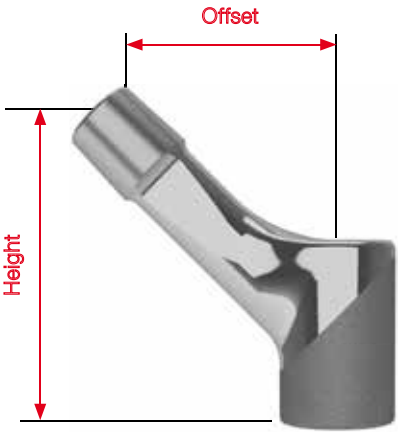
LATERALIZED – 125° :

- Taper A – with Head M (+0 mm)

SIZE	Ø	OFFSET	HEIGHT
S	16 mm	27 mm	41 mm
L	16 mm	36 mm	44 mm

- Taper B – with Head M (+0 mm)

SIZE	Ø	OFFSET	HEIGHT
S	19 mm	32 mm	42 mm
L	19 mm	41 mm	48 mm
Large S	23 mm	32 mm	42 mm
Large L	23 mm	41 mm	48 mm



CCD 125°

PRE-OPERATIVE PLANNING

Important. *Pre-operative planning provides useful information for determining probable implant size and for identifying accurately femoral neck osteotomy level.*
The level of osteotomy should be carefully planned especially in the outcomes of previous osteotomy.

Note. *The final and correct stem size must be determined during surgery.*
Where it is possible to match the size planned, the height of the positioning has to consider the soft tissue tension during trial reduction, and the quality of the bone.

Figure 1

To achieve the best results, pre-operative planning using special templates (showing 15% larger profiles) is always advisable.

Good quality frontal and an axial X-Ray with adequate contrast should be used; it should cover the entire length of the pre-operative clear films of the stem profile *(Fig.1)*.
Instead of conventional templates, a digital version compatible with most surgical planning software is also available.

When suitable determine the neck resection level by matching the apex of the greater trochanter to the centre of the medium femoral head *(Fig. 2)*.
However, the main feature of the conical modular stem is the possibility to create the location for the stem itself, distally or proximally in the femoral shaft according to the needs of the anatomy of the case addressed, specifically in the dysplastic hip, where either a shortening or a lengthening of the limb could be advised. In the planning, the location can be decided.

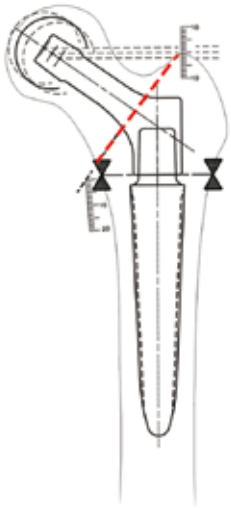


Figure 2

Note. *Templates are used to identify the resection plane in the pre-operative planning stage.*

Neck Resection

NECK RESECTION

After dislocating the femur, femoral head resection *(Fig.3)* is made by using the anatomical landmarks referenced during pre – operative planning.

Figure 3

FEMORAL CANAL PREPARATION

Start opening the medullary cavity with the box osteotome *(Fig. 4)*.

Figure 4

Femoral Reaming

FEMORAL REAMING

Assemble the smallest reamer, size 14, to the T-wrench *(Fig.5a)* and start reaming *(Fig.5b)*.
Widen the medullary canal with incrementing size reamers until noticeable resistance is felt.

Check for etch/witness marks alignment corresponding to the apex of the greater trochanter *(Fig.6)*.
Note: if the greater trochanter is damaged please select a different reference point in the anatomy.

Note: *Etch/witness marks on the reamer handle allow size (diameter) adjustment of 1 mm depending on the depth of the final seated reamer (Fig.7).*

Figure 5a

Figure 5b

Figure 6

Figure 7

STEM TRIAL

Figure 8

When reaming is complete, select the stem trial of the same diameter as the final reamer.

Note. *Remove the sliding hammer from the manual impactor (Fig.8).*

Thread the manual impactor into the stem trial *(Fig.9)*. Insert the stem trial into the femur *(Fig.10)* until the depth mark '0' is aligned to the apex of the greater trochanter *(Fig.11)*. Hammer blows should be of moderate strength .

Figure 9

Check for axial and rotational (clockwise) stability.

Note. *The under-dimensioned fins and the polished finish render the stem trial less stable than the definitive stem.*

If the stem trial is not stable, use the next size up trial (equivalent to the +10 mark on the handle). If needed ream again.

Figure 10

Note. *Due to local anatomical anomaly, the tip of the greater trochanter may stick out interfering medially with the insertion. Check for correct femoral/medullary canal alignment, avoiding tilting in varus. The apex of the GT can be violated for the diameter of the reamer/stem, without any consequence.*

Figure 11a

Figure 11b

Neck Site Preparation

Figure 12a

Figure 12b

NECK SITE PREPARATION

Unthread the manual impactor. Thread the neck guide rod into the trial stem to properly ream over the taper junction. *(Fig.12a, b)*

The reamer guide sets the trajectory and depth for neck reaming. Select the neck reamer based on the stem taper *(Fig.13a, b, c)*.

Figure 13a

FIGS.	SIZE (Ø)	MODULAR NECK	VISUAL LEGEND
13a	13 – 15	A	No grooves
13b	16 – 20	B	Single groove
13c	21 – 26	B – Large	Double groove

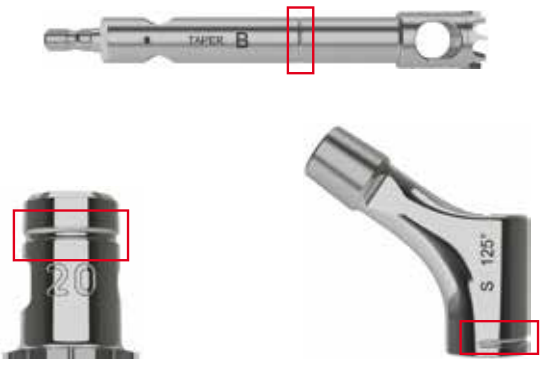


Figure 13b

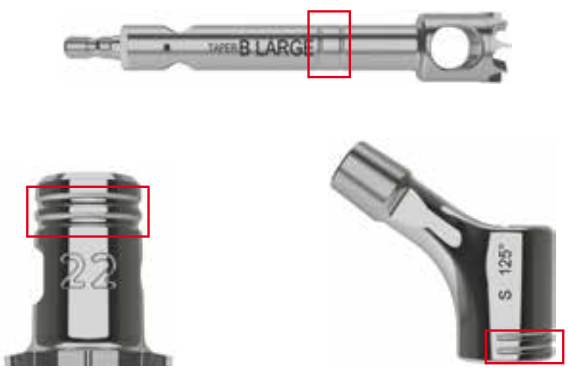


Figure 13c

Figure 14

Assemble the selected reamer with the T-Handle *(Fig.14)* and start reaming the metaphysis *(Fig.15)* until it no longer advances. For B-Large necks, B reaming can proceed the B-Large reaming.

To verify that the reamer is fully seated and the proper reaming depth is obtained insert a Kirschner wire through the proximal (pin) hole:

a) if it does go through continue reaming *(Fig.16a)*,

b) if it does not go through stop reaming *(Fig.16b)*.

Figure 15

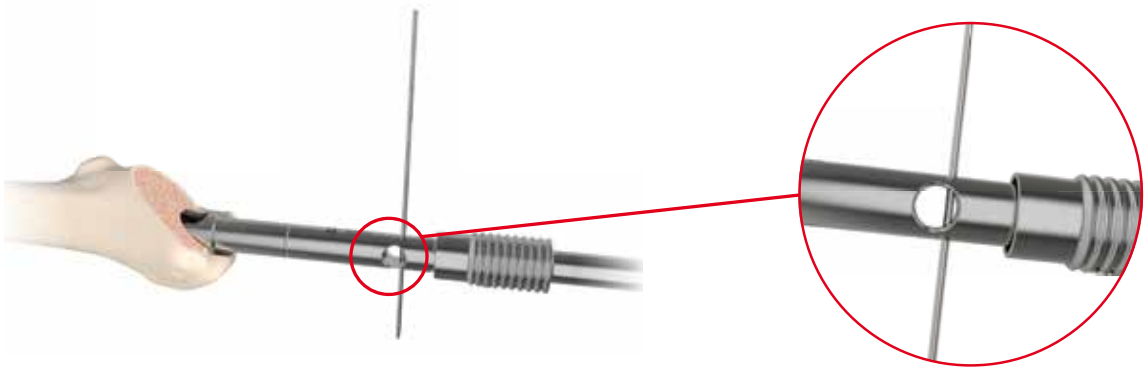


Figure 16a: WRONG, need to ream more.

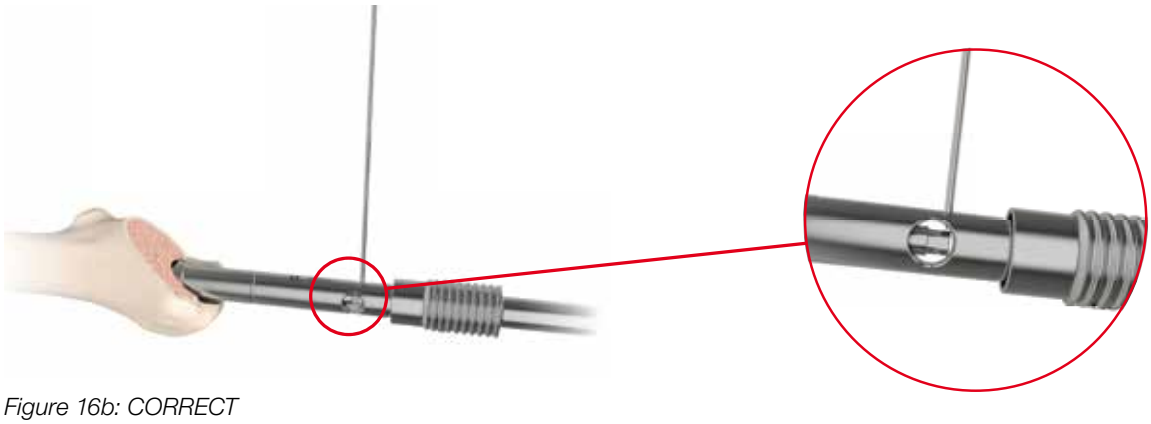


Figure 16b: CORRECT

Trial Reduction

Figure 17

Figure 18a

Figure 18b

Figure 19

TRIAL REDUCTION

Acetabular preparation must be completed.

Clean and dry the taper junction of the distal stem.
Place the neck trial, through the guide, onto the trial stem taper junction *(Fig.17)*. Remove the neck guide rod by turning the hex key counter-clockwise.
Lock the neck trial with the locking screw trial *(Fig.18a)* while maintaining correct anteversion with the neck stopper *(Fig.18b)*.

Utilizing modular head trials, perform a trial reduction *(Fig.19)*. Component position, joint stability, range-of-motion and leg length are checked. Assess what adjustments, if any, are required to ensure stability through a full range of motion check. When stability is achieved, use the neck trial reference mark to mark the bone, to achieve exact definitive neck positioning.

Remove neck and stem trials.

STEM INSERTION

Select the stem size that corresponds to the stem trial.

Thread the impactor onto the MODULUS distal body *(Fig.20)*. Insert the stem into the femur *(Fig.21)* until the depth mark '0' is aligned to the apex of the greater trochanter (or to the anatomical point selected as reference), complete seating and appropriate primary stability of the stem are achieved *(Fig.22)*. Hammer blows should be of moderate strength.

Check stem trial axial and rotational stability (clockwise).

Further trial reduction, with the neck and head trials, can be performed following the same procedure described before.

Figure 20

Figure 21

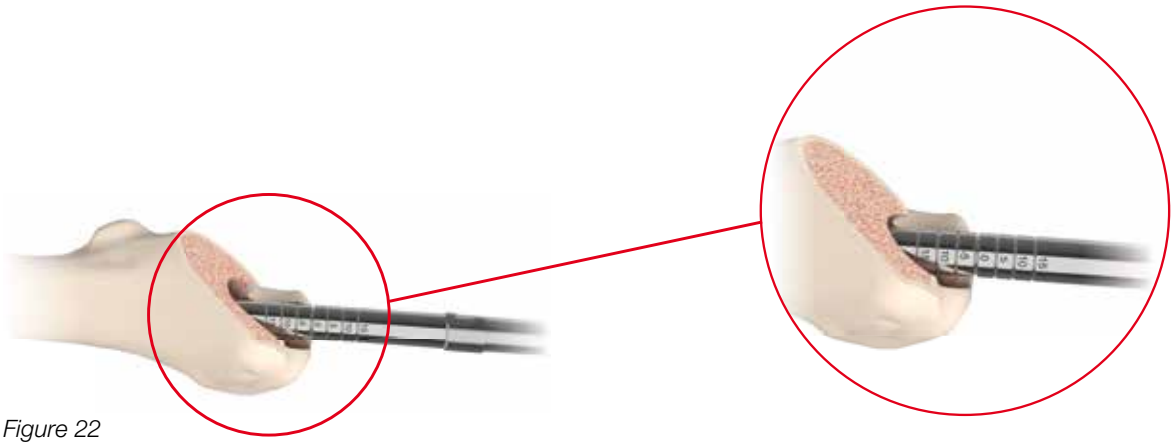


Figure 22

Neck Insertion

Figure 23

Figure 24

Figure 25

Figure 26

NECK INSERTION

Important. *Carefully clean and dry the taper junction of the distal stem ensuring it is free of debris.*

Thread the neck guide rod onto the MODULUS stem (*Fig.23)*.

Place the MODULUS neck, through the guide, onto the stem taper junction *(Fig.24)*. Neck position, especially anteversion, should follow the previously marked anatomical landmark.
Achieve a steady neck-stem coupling by hammering the definitive neck with the apposite impactor *(Fig.25)*, slid onto the neck guide.

Remove the neck guide rod by turning the hex key counter-clockwise.

To grant accurate coupling of the Morse taper, lock firmly the safety screw *(Fig.26)*, while maintaining anteversion with the aid of the neck stopper *(Fig.27)*.

Figure 27

Figure 28

FEMORAL HEAD INSERTION

Clean and dry the taper thoroughly, ensuring it is free of debris. Place the appropriate femoral head onto the taper; engage it by pushing and twisting *(Fig.28)*. Then strike the definitive head with the apposite impactor *(Fig.29)*.

Note: *The head impactor has an internal double concavity, allowing its use with all head diameters (28, 32, 36 and 40 mm).*

Clean the bearing surfaces and reduce the hip *(Fig.30)*.

Figure 29

Figure 30

Figure 31

Figure 32

Figure 33

Figure 34

Figure 35

COMPONENTS REMOVAL

If necessary the various prosthetic components can be removed. The femoral head can be removed by simply tapping the base of the head axially using an impactor.

IMPORTANT. *If only the head needs removing and replacing with a new ceramic head, always use ceramic revision heads (on request only) which have a Titanium safety sleeve.*

DISENGAGING THE TAPER JUNCTION

1. Unscrew the safety screw *(Fig.31)*.
2. Disassemble the neck extractor's two components *(Fig.32)*.
3. Thread and tighten the outer sleeve into the Modulus neck *(Fig.33)*.
4. With the aid of the T- wrench, screw the pushing rod (of the neck extractor) into the outer sleeve *(Fig.34)*, holding in place the latter.
5. Remove the T-wrench *(Fig.35)*.
6. Hammer onto the pushing rod, while keeping steady the outer sleeve.
7. Reassemble the T-wrench onto the pushing rod and tighten the rod again.
8. If the neck is still engaged, continue the iterative process, from step 4, until the taper junction disengages.

Note. *Hammering on the pushing rod, producing vibrations, eases the removal process.*

Figure 36

REMOVING THE MODULUS DISTAL COMPONENT

Make sure the slap hammer is mounted on the manual impactor *(Fig.36)*.

Thread the manual impactor onto the MODULUS distal component and, with upward movements of the slap hammer, extract the stem *(Fig.37)*.

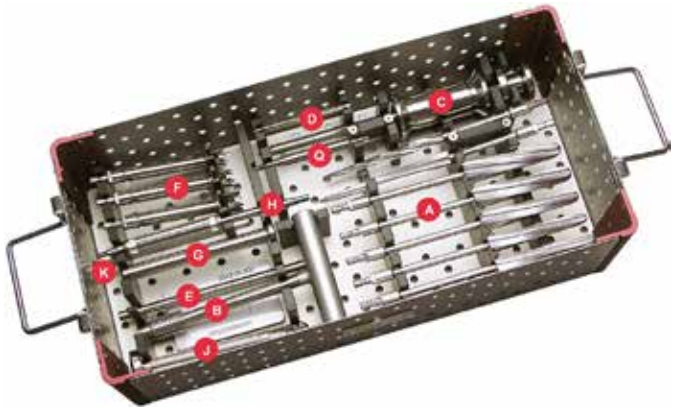
IMPORTANT. *This method may be used in cases where biological fixation is absent or weak; otherwise it is necessary to separate the integrated surfaces of the bone using suitable small scalpels or Kirschner wires. In some cases a Wagner femoral osteotomy may be required.*

Figure 37

MODULUS FEMORAL STEM SURGICAL TECHNIQUE

Instrument Set

▼ 9043.20.000 Instrument set for MODULUS femoral stem

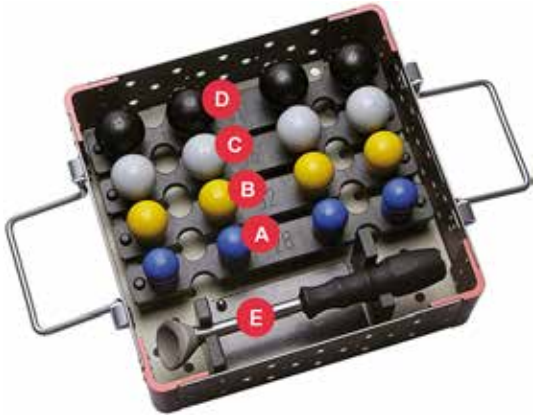


Ref.	CODE	DESCRIPTION	Qty.
A	9043.10.140	Reamer Dia. 14mm	1
A	9043.10.160	Reamer Dia. 16mm	1
A	9043.10.180	Reamer Dia. 18mm	1
A	9043.10.200	Reamer Dia. 20mm	1
A	9043.10.220	Reamer Dia. 22mm	1
A	9043.10.240	Reamer Dia. 24mm	1
A	9043.10.260	Reamer Dia. 26mm	1
B	9095.10.131	H210 Wrench for Zimmer Connection	1
C	9043.10.310	Manual Impactor	1
D	9043.10.315	Neck Reamer Guide	1
E	9043.10.320	Allen Wrench	1
F	9043.10.330	Neck Reamer A	1
F	9043.10.340	Neck Reamer B	1
F	9043.10.345	Large Neck Reamer B	1
G	9043.10.350	Neck Impactor	1
H	9043.10.360	Neck Extractor	1
I	9043.10.370	Neck Stopper	1
J	9043.10.380	Canal Chisel	1
K	9043.10.390	Dia. 16mm Wrench	1
L	9043.10.400	Trial Locking Screw for Neck-Stem	2
M	9043.10.410	Trial Neck Short 125° Taper A	1
M	9043.10.420	Trial Neck Long 125° Taper A	1
M	9043.10.500	Trial Neck Short 135° Taper A	1
M	9043.10.510	Trial Neck Long 135° Taper A	1
N	9043.10.430	Trial Neck Short 125° Taper B	1
N	9043.10.440	Trial Neck Long 125° Taper B	1
N	9043.10.520	Trial Neck Short 135° Taper B	1
N	9043.10.530	Trial Neck Long 135° Taper B	1
O	9043.10.450	Trial Neck Short 125° Large Taper B	1
O	9043.10.460	Trial Neck Long125° Large Taper B	1
O	9043.10.540	Trial Neck Short 135° Large Taper B	1
O	9043.10.550	Trial Neck Long 135° Large Taper B	1
P	9043.10.600	Trial Stem Dia. 13mm Taper A	1
P	9043.10.610	Trial Stem Dia. 14mm Taper A	1
P	9043.10.620	Trial Stem Dia. 15mm Taper A	1
P	9043.10.650	Trial Stem Dia. 16mm Taper B	1
P	9043.10.660	Trial Stem Dia. 17mm Taper B	1
P	9043.10.670	Trial Stem Dia. 18mm Taper B	1
P	9043.10.680	Trial Stem Dia. 19mm Taper B	1
P	9043.10.690	Trial Stem Dia. 20mm Taper B	1
P	9043.10.700	Trial Stem Dia. 21mm Taper B	1
P	9043.10.710	Trial Stem Dia. 22mm Taper B	1
P	9043.10.720	Trial Stem Dia. 23mm Taper B	1
P	9043.10.730	Trial Stem Dia. 24mm Taper B	1
P	9043.10.740	Trial Stem Dia. 25mm Taper B	1
P	9043.10.750	Trial Stem Dia. 26mm Taper B	1
Q	9095.10.134	Allen Wrench for Zimmer Connection	1
R	9095.10.711	Trial Head Taper 12/14 Dia. 28mm S	1
R	9095.10.712	Trial Head Taper 12/14 Dia. 28mm M	1
R	9095.10.713	Trial Head Taper 12/14 Dia. 28mm L	1
	9043.20.950	Sterilizable Box	1

MODULUS FEMORAL STEM SURGICAL TECHNIQUE

Additional Instrument Set

▼ 9095.50.000 Instrument set for trial heads



Ref.	CODE	DESCRIPTION	Qty.
A	9095.10.711	Trial Head Dia. 28mm S	1
A	9095.10.712	Trial Head Dia. 28mm M	1
A	9095.10.713	Trial Head Dia. 28mm L	1
A	9095.10.714	Trial Head Dia. 28mm XL	1
B	9095.10.721	Trial Head Dia. 32mm S	1
B	9095.10.722	Trial Head Dia. 32mm M	1
B	9095.10.723	Trial Head Dia. 32mm L	1
B	9095.10.724	Trial Head Dia. 32mm XL	1
C	9095.10.731	Trial Head Dia. 36mm S	1
C	9095.10.732	Trial Head Dia. 36mm M	1
C	9095.10.733	Trial Head Dia. 36mm L	1
C	9095.10.734	Trial Head Dia. 36mm XL	1
D	9095.10.741	Trial Head Dia. 40mm S	1
D	9095.10.742	Trial Head Dia. 40mm M	1
D	9095.10.743	Trial Head Dia. 40mm L	1
D	9095.10.744	Trial Head Dia. 40mm XL	1
E	9095.11.110	Femoral Head Impactor	1
	9095.50.950	Sterilizable Box	1

MODULUS FEMORAL STEM SURGICAL TECHNIQUE

Product Codes

MODULUS Stem - Size (Ø) 20 mm

MODULUS STEMS

CODE	SIZE (Ø)	TAPER	NECKS
4310.10.010	13 mm	A	A
4310.10.020	14 mm	A	A
4310.10.030	15 mm	A	A
4310.15.045	16 mm	B	B
4310.15.050	17 mm	B	B
4310.15.060	18 mm	B	B
4310.15.070	19 mm	B	B
4310.15.080	20 mm	B	B
4310.15.090	21 mm	B	B – Large
4310.15.100	22 mm	B	B – Large
4310.15.110	23 mm	B	B – Large
4310.15.120	24 mm	B	B – Large
4310.15.130	25 mm	B	B – Large
4310.15.140	26 mm	B	B – Large

Neck Taper B – CCD 135° short/ long

MODULUS NECKS

STANDARD – 135°

CODE	TAPER	SIZE
7595.15.010	A	S
7595.15.020	A	L
7595.15.030	B	S
7595.15.040	B	L
7595.15.050	B-Large	S
7595.15.060	B-Large	L

LATERALIZED – 125°

CODE	TAPER	SIZE
7590.15.010	A	S
7590.15.020	A	L
7590.15.030	B	S
7590.15.040	B	L
7590.15.050	B-Large	S
7590.15.060	B-Large	L

Neck Taper B – CCD 125° short/long

Note. In order to better indentify correspondence between stem and neck a colored green label ( ) will identify the Taper A and a white label ( ) will indentify the Taper B.

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