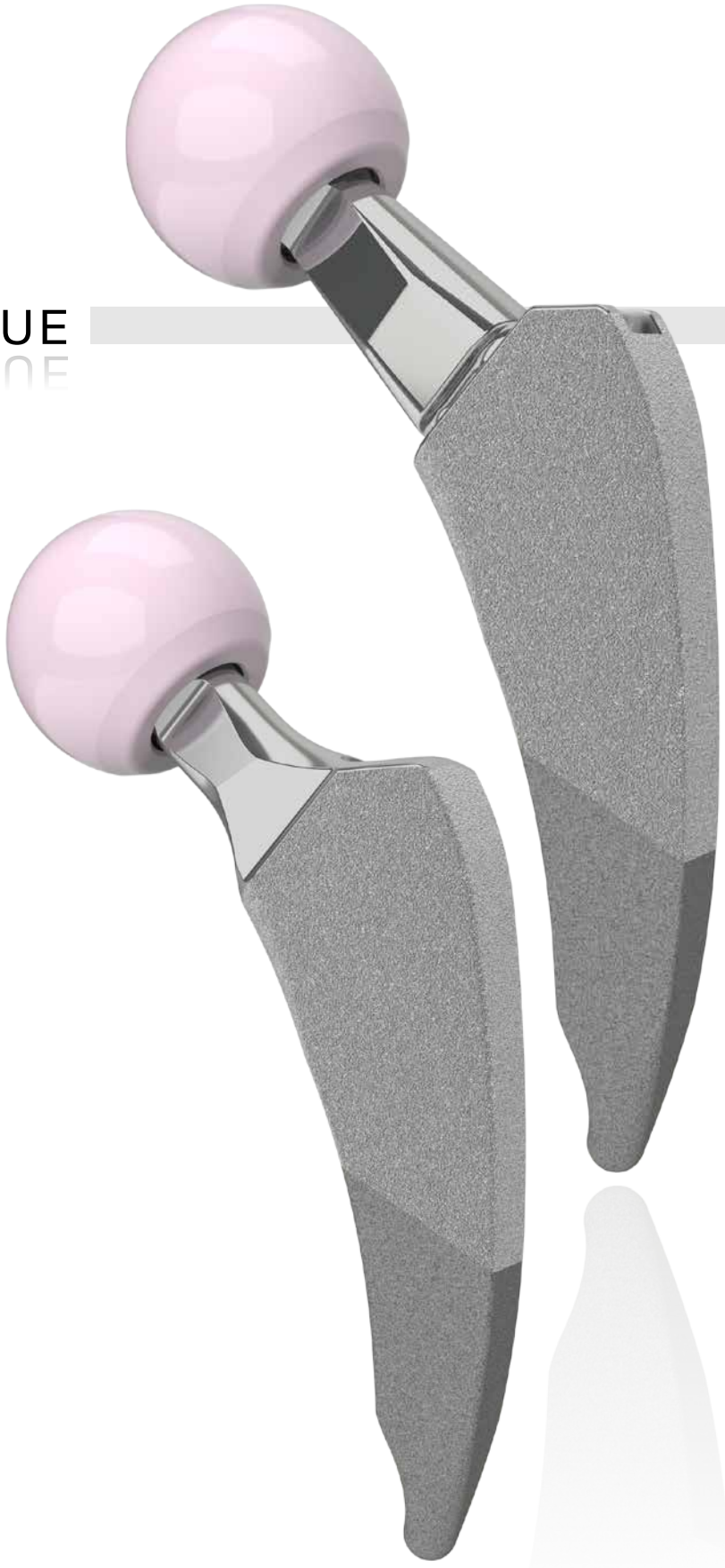
MINIMA SYSTEM

SIMPLE RELIABLE

SURGICAL TECHNIQUE



Lima Corporate
Orthopaedic motion

MINIMA SYSTEM SURGICAL TECHNIQUE

Index

Limacorporate S.p.A. is a manufacturer of prosthetic implants and as such does not perform medical procedures. This documentation concerning surgical techniques, which provides surgeons with general guidelines for implanting the MINIMA stem, was developed with the advice of a team of surgical experts. All decisions as to the type of surgery and most suitable technique are obviously the responsibility of the health care professional. Surgeons must make their own decisions as to the adequacy of each planned implant technique based on their training, experience and the clinical condition of the patient.

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

MINIMA SYSTEM SURGICAL TECHNIQUE
Indications and Contraindications

INDICATIONS

Cementless MINIMA femoral stems are used for the total or partial replacement of the hip joint and are intended to be used without cement.

For total joint replacements, the MINIMA femoral stems are combined with modular heads and compatible acetabular components. For partial joint replacements, the stems are combined with the appropriate uni- or bipolar heads.

Hip replacements are performed to reduce pain and/or improve joint function in adult patients suffering from the following problems:

1. non-inflammatory degenerative joint diseases such as osteoarthritis, avascular necrosis and hip dysplasia;
2. rheumatoid arthritis;
3. femoral head or neck fractures;
4. functional deformities (MINIMA M);
5. revision surgery if the femoral bone stock is sufficiently well preserved;

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

CONTRAINDICATIONS

Absolute contraindications:

1. local or systemic infection;
2. septicaemia;
3. persistent chronic or acute osteomyelitis;
4. evidence of compromised joint function due to nerve or muscle damage;
5. renal failure

Relative contraindications:

1. vascular or nerve damage to the limb requiring surgery;
2. poor bone trophism (e.g. due to osteoporosis) that could compromise the stability of the implant;
3. metabolic disorders that could jeopardise the fixation and stability of the implant;
4. certain concomitant diseases and addictions that could compromise the success of the implant;
5. hypersensitivity towards implant metals.

WARNINGS

Surgeons must carefully plan the procedure after viewing the surgical technique to be used to insert the stem. Particular attention should be focussed on the following aspects:

1. **small sized stems:** small sized stems are designed for patients with a small intramedullary canal and/or metaphyseal region. The smaller medio-lateral width of these stems means that the implant's stress resistance is correspondingly lower;
2. **combinations with extended offset (i.e. use of lateralising stems):** lateralising stems are designed to restore the functional offset of the hip joint, so it is comparable with that of the opposite joint. However, longer neck lengths are associated with a higher risk of failure (for instance, stress fracture).

Complications and failures are more likely to affect overweight or active patients, and extended offset combinations.

ALLOWED/PROHIBITED COMBINATIONS

For the MINIMA M stem, the following combinations of **modular necks and femoral heads are allowed:**

1. except for LONG (#LAT-L) lateralising modular necks, modular necks may be coupled only with S, M, L and XL femoral heads;
2. LONG (#LAT-L) lateralising modular necks may be coupled only with S, M and L femoral heads;

The use of modular necks with longer heads may lead to implant failures (for instance, stress fracture).

Modular necks in Ti6Al4V must be used only in patients with CoCrMo allergy.

IMPORTANT: *To assess stress resistance, MINIMA stems have been tested in accordance with ISO standards. Combinations with #XXL or #XXXL heads have not been tested. Should the surgeon decide to use #XXL or #XXXL heads in order to achieve the desired joint stability, the risks associated with extended offset combinations must be carefully considered.*

RISK FACTORS

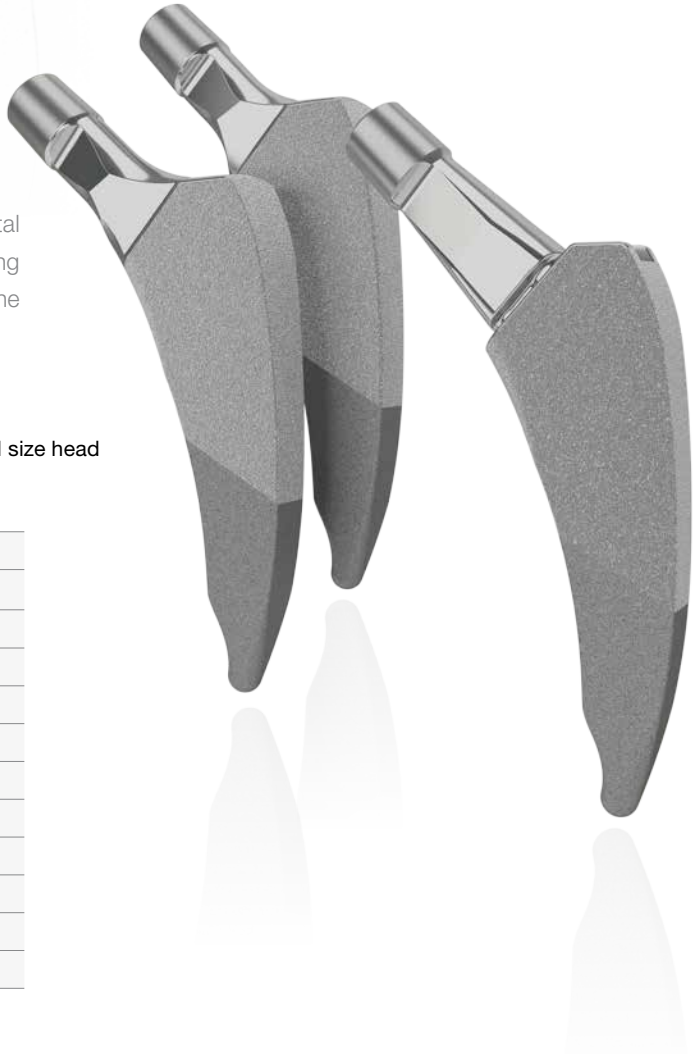
Risk factors that could lead to unsatisfactory results in the use of this implant include:

1. overweight;
2. excessive physical activity (sport or work related);
3. improper implant position (e.g. varus positioning);
4. multiple joint disabilities;
5. muscle deficiency;
6. medical disabilities that could lead to unnatural gait and hip loading;
7. patient refusal to modify physical activity after surgery;
8. previous history of infections or falls;
9. systemic diseases and metabolic disorders;
10. localised neoplastic or metastatic disease;
11. drug treatments affecting bone quality, healing or resistance to infection;
12. drug or alcohol addiction;
13. marked osteoporosis or osteomalacia;
14. patients affected by diseases causing weakening (e.g. AIDS, cancer and infections);
15. severe malformations leading to inadequate fixation or improper implant positioning;
16. fretting of modular components;
17. undersized stem.

MINIMA SYSTEM SURGICAL TECHNIQUE

Stem sizes

The monolithic and modular version of the MINIMA SYSTEM is comprised of 12 stem sizes. The standard versions have a neck-shaft angle of 134°, while the lateralising versions have a neck-shaft angle of 131°.
Stems dimensions increase with larger sizes; in the frontal plane, the width increases in 0.7 mm increments for sizes going from 1 to 10 and in 1 mm increments for sizes 11 and 12; in the medial plane the thickness increases by 0.2 mm per size.



OFFSET TABLE FOR MINIMA S - monolithic stem with M size head

Size	STD	LAT
1	34.1 mm	39.1 mm
2	35.0 mm	40.0 mm
3	36.0 mm	41.0 mm
4	36.9 mm	41.9 mm
5	38.0 mm	43.0 mm
6	39.0 mm	44.0 mm
7	40.0 mm	45.0 mm
8	41.1 mm	46.0 mm
9	42.2 mm	47.2 mm
10	43.3 mm	48.3 mm
11	44.4 mm	49.4 mm
12	45.5 mm	50.5 mm

OFFSET TABLE FOR MINIMA M - modular stem with M size head

Size	STD SHORT NECK STD-S (S1)	STD LONG NECK STD-L (L1)	LAT SHORT NECK LAT-S (S4)	LAT LONG NECK LAT-L (L4)
1	34.7 mm	42.1 mm	39.7 mm	47.1 mm
2	35.1 mm	42.5 mm	40.1 mm	47.5 mm
3	35.6 mm	43,0 mm	40.6 mm	48.0 mm
4	36.1 mm	43.5 mm	41.1 mm	48.5 mm
5	36.5 mm	43.9 mm	41.5 mm	48.9 mm
6	37.1 mm	44.5 mm	42.1 mm	49.5 mm
7	37.6 mm	45.0 mm	42.6 mm	50.0 mm
8	38.4 mm	45.8 mm	43.4 mm	50.8 mm
9	38.8 mm	46.2 mm	43.8 mm	51.2 mm
10	39.5 mm	46.9 mm	44.5 mm	51.9 mm
11	40.2 mm	47.6 mm	45.2 mm	52.6 mm
12	40.8 mm	48.2 mm	45.8 mm	53.2 mm

Pre-Operative planning

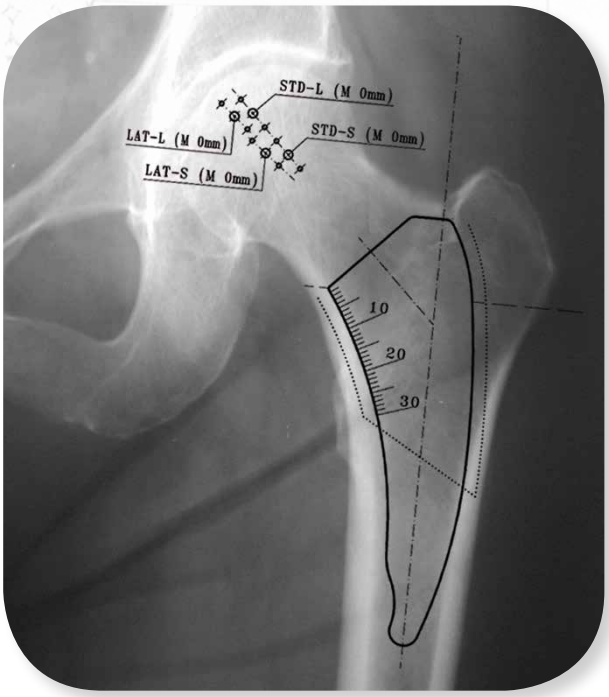


Figure 1
X-Ray with modular stem template.

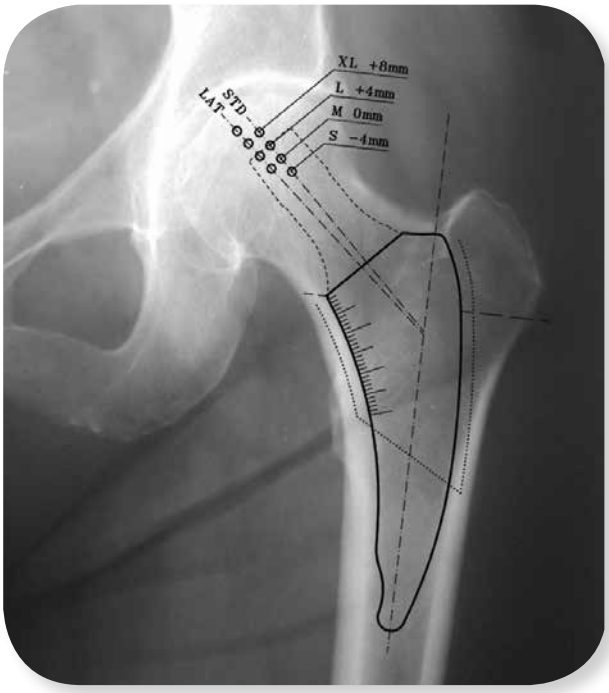


Figure 2
X-Ray with monolithic stem template.

IMPORTANT: *Pre-operative planning provides useful information for the correct placement of the implant but does not necessarily indicate the appropriate stem size. The correct stem size must be determined during surgery.*

PRE-OPERATIVE PLANNING

To achieve the best results, pre-operative planning using special templates (showing 15% larger profiles) is always advisable.
A 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. 1-2)*.

Instead of conventional templates, a digital version compatible with most surgical planning software is also available.

STEM SIZE SELECTION

It is important to note that this stem achieves proximal fixation.

First determine the correct stem size to ensure that the contour lines of the proximal region fills the epiphyseal region of the femur. Check on the axial projection that the stem does not interfere with the anterior curvature of the femur.

For the MINIMA M, determine the correct neck size and type so as to restore the correct centre of rotation, checking the degree of anteversion in the sagittal plane. Determine the neck resection level, aligning the tip of the greater trochanter with the centre of the medium femoral head.

In case a monolithic stem is used, the templates show the centres of rotation in two versions for the various head lengths *(Fig. 4)*. If the modular stem is used, the templates show the centres of rotation of the head in the neck versions (Standard-Short, Standard-Long, Lateralising-Short, Lateralising-Long) for the various head lengths.

The modular stem templates also show the centres of rotation in the lateral view for the Standard-Short and Standard-Long versions *(Fig. 3)*.

IMPORTANT: *Templates are used to identify the resection plane in the pre-operative planning stage. Any changes must be decided at this time.*

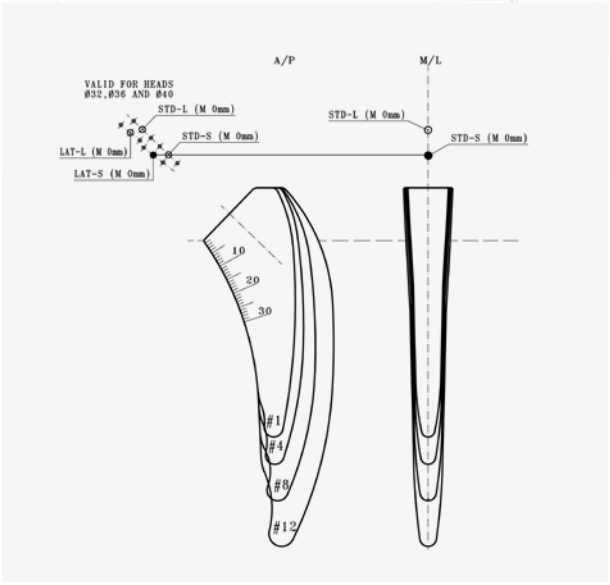


Figure 3

Template overlay of MINIMA M modular stems with Centre of Rotation

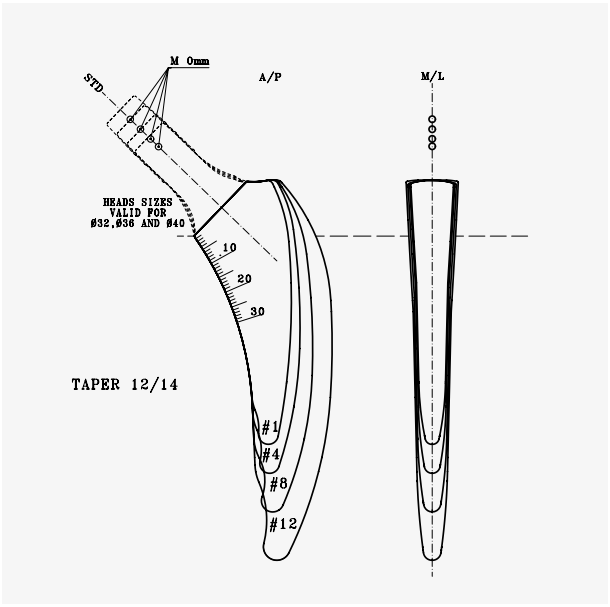


Figure 4

Template overlay of STD MINIMA S stems with Centre of Rotation

MINIMA SYSTEM SURGICAL TECHNIQUE
Neck resection

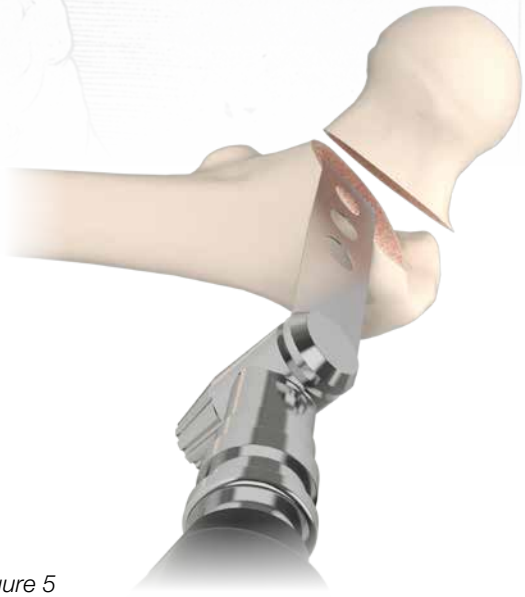


Figure 5

NECK RESECTION

After dislocating the femur, resect the femoral head *(Fig. 5)*.

Figure 6

REAMING AND BROACHING

Begin approaching the canal by driving the canal chisel into the cancellous bone *(Fig. 6)*.

Then open the canal using a curved rasp *(Fig. 7)*.

The instrument set includes several rasps *(Fig. 8)* to be mounted on rasp handles.

Figure 7

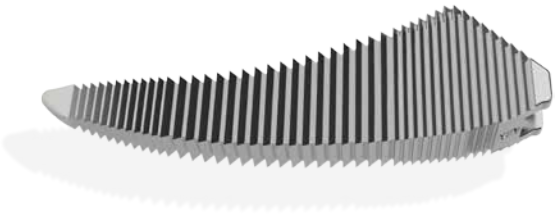


Figure 8

MINIMA SYSTEM SURGICAL TECHNIQUE

Reaming and Broaching

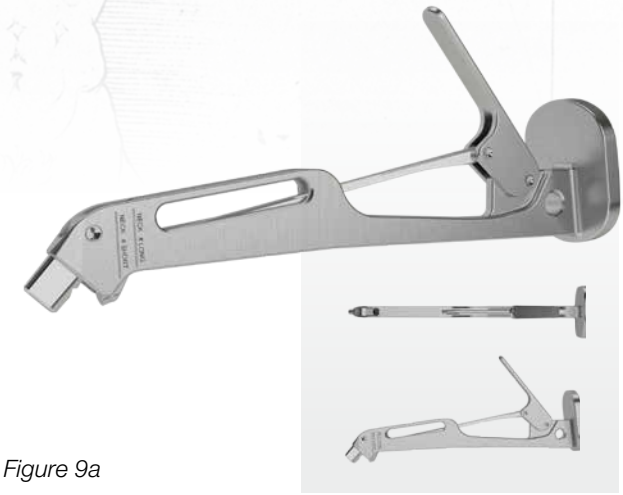


Figure 9a

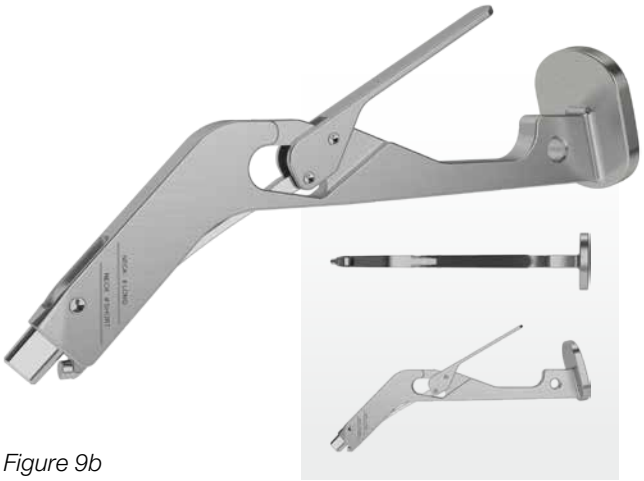


Figure 9b

Figure 9c

These hand come in three versions, straight, anterior offset and lateral offset, to accommodate different surgical approaches *(Fig. 9 a, b, c)*.

Reaming and Broaching

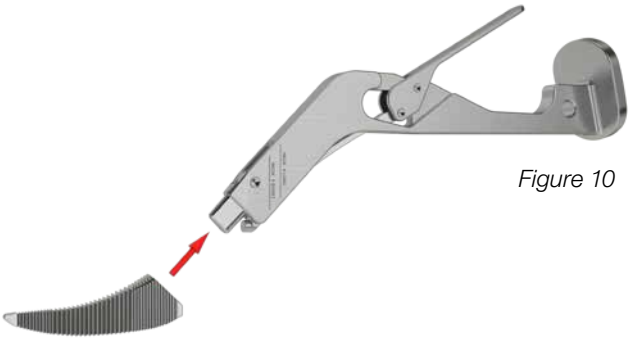


Figure 10

To connect the rasp to the handle, raise the lever and couple the broach with the medial side facing the side of the lever *(Fig. 10)*.

Tighten the lever until it closes *(Fig. 11)*.

Figure 11

MINIMA SYSTEM SURGICAL TECHNIQUE

Reaming and Broaching

Figure 12

Begin broaching the canal with the smallest broach, retaining the correct anteversion *(Fig. 12)*.
Drive the broach into the canal until the sloped plane of the rasp matches the resection plane *(Fig. 13-14)*.

Figure 13

Figure 14

Figure 15

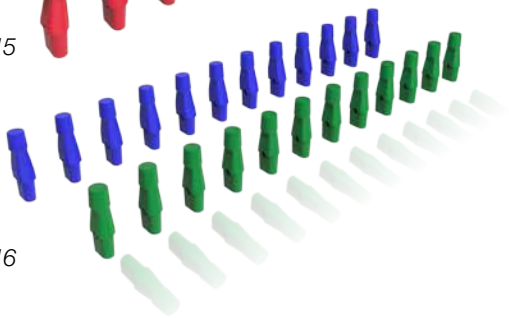


Figure 16

TRIAL REDUCTION

In case the acetabular component is implanted before the femoral stem, a trial reduction can be performed.

For the modular stem, the instrument kit includes trials for the 12 modular Short (red) and Long (grey) necks *(Fig. 15)*.

For the monolithic stem, the instrument set includes trial necks for each size in the Standard (green) and Lateralising (blue) version *(Fig. 16)*.

Select the correct trial neck and insert the trial neck using the appropriate instrument *(Fig. 17-18)*.

Figure 17

Figure 18

MINIMA SYSTEM SURGICAL TECHNIQUE

Trial reduction

Insert the trial head *(Fig. 19)* and perform the trial reduction *(Fig. 20)*.

Figure 19

Figure 20

Trial reduction

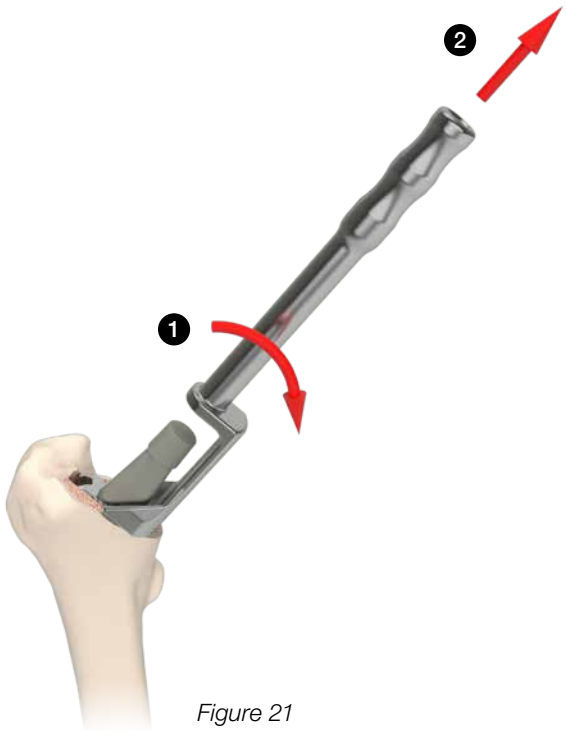


Figure 21

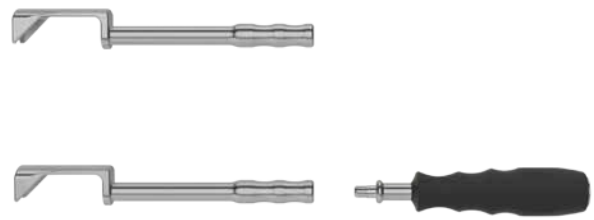


Figure 22

Remove the trial neck using the neck extractor *(Fig. 21)* which can be used in two different configurations *(Fig. 22)*:

a: Leveraging only with the extractor;
b: Leveraging with the silicone handpiece screwed on to the extractor

Each trial neck comes with its own code number that is also printed on the packaging of the final neck, to facilitate the selection process. For example:

S1 = standard short neck;
L1 = standard long neck;
S2 = standard short AVR/RVL neck;
L2 = standard long AVR/RVL neck;
S3 = standard short AVL/RVR neck;
L3 = standard long AVL/RVR neck;
S4 = short LAT neck;
L4 = long LAT neck;
S5 = short LAT AVR/RVL neck;
L5 = long LAT AVR/RVL neck;
S6 = short LAT AVL/RVR neck;
L6 = long LAT AVL/RVR neck;

MINIMA M definitive stem insertion

Figure 23

Figure 24

Figure 25

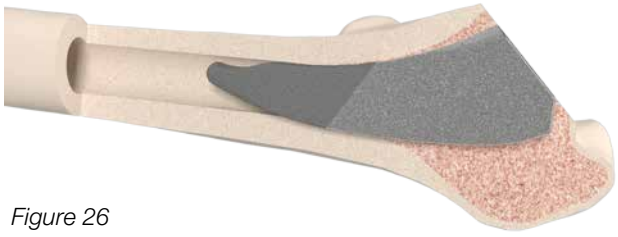


Figure 26

MINIMA M DEFINITIVE STEM INSERTION

Remove the sterile packaging from the Modular stem in the size corresponding to the last broach used *(Fig. 23)*.

Use the rasp handle to impact the stem into place, until the sloped plane of the stem is aligned with the rasp *(Fig. 24-25-26)*.

Check the neck again by inserting the chosen trial neck onto the final stem.

MINIMA M definitive stem insertion

Figure 27

Thoroughly clean and dry the stem cavity. Remove the definitive neck from the sterile packaging; the code number must match that of the trial neck. Position the neck into the cavity of the final stem *(Fig. 27)*.

Impact along the length of the positioner to drive the neck into place *(Fig. 28)*.

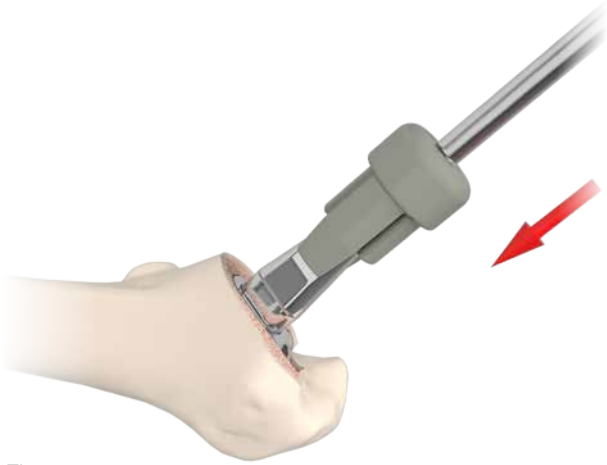


Figure 28

MINIMA S definitive stem insertion

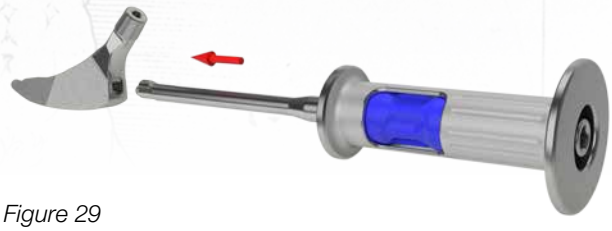


Figure 29

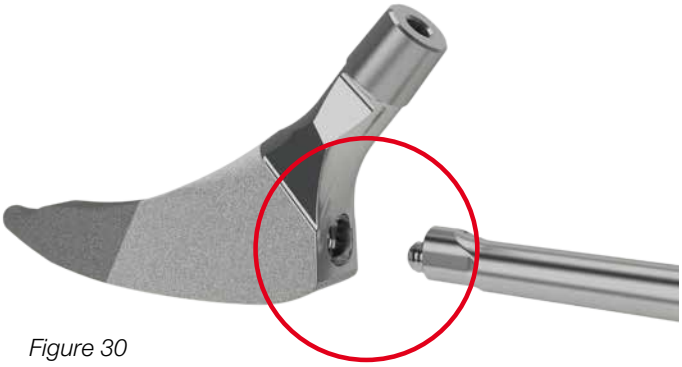


Figure 30

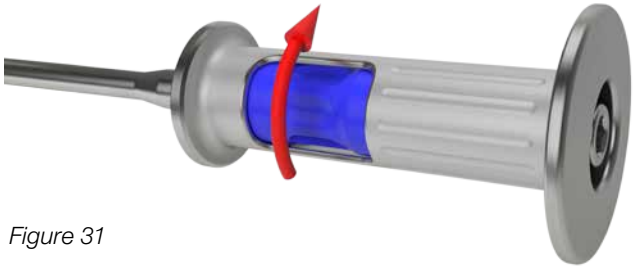


Figure 31

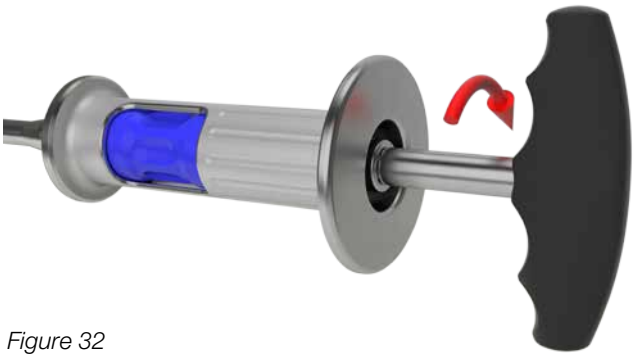


Figure 32

MINIMA S DEFINITIVE STEM INSERTION

Remove the stem from the sterile packaging in the size corresponding to the last broach used.

The stem may be implanted using a screw impactor (A) or an unconstrained offset impactor (B).

A – Screw the stem positioner onto the final stem exactly as shown *(Fig. 29-30)* rotating the washer manually *(Fig. 31)*; the T-wrench can be used to lock the stem into the handpiece of the stem positioner *(Fig. 32)*.

Once the T-wrench has been removed, impact the stem into place up to the level reached by the broach.

Unscrew the handlpiece of the stem impactor.

MINIMA S definitive stem insertion

Figure 33

B – Manually insert the stem into the femoral cavity, align the curved impactor with the impactor seat on the lateral side of the stem *(Fig. 33)* and impact until fully inserted.

The line separating the Porous Titanium coating and the polished surface corresponds to the broach profile *(Fig. 34)*.

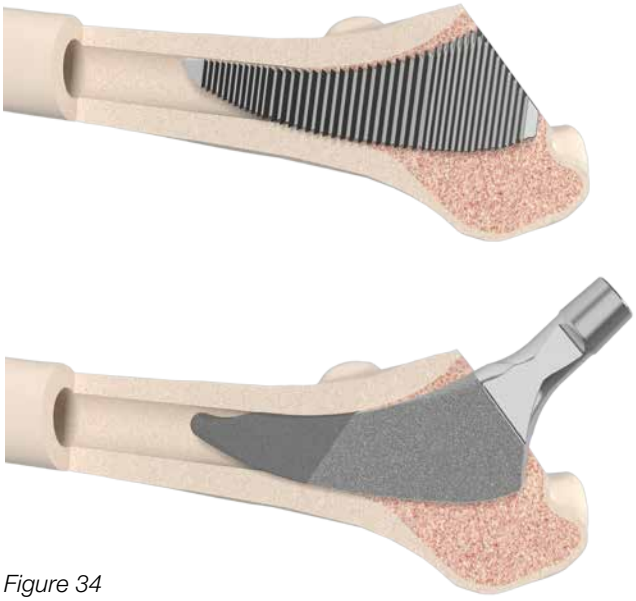


Figure 34

Definitive head insertion

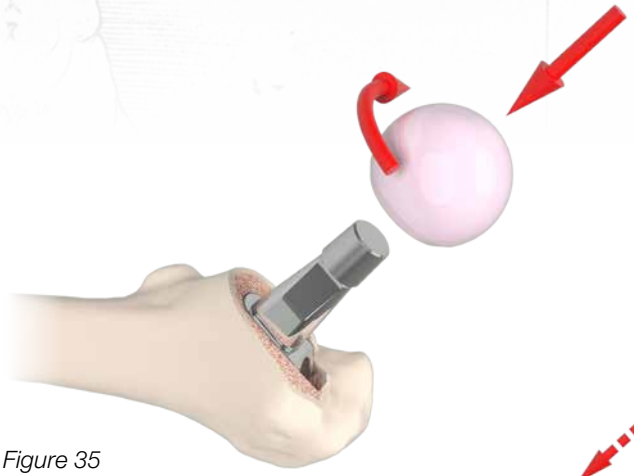


Figure 35

Figure 36

Figure 37

DEFINITIVE HEAD INSERTION

Once the correct head size, diameter and material have been determined on a case by case basis, the length of the head can be rechecked using the trial heads.

Remove the component from the sterile packaging of the appropriate diameter and length. Thoroughly clean and dry the neck taper. This is an essential step especially for ceramic heads; remove the protective cap then press and twist the head along the neck axis *(Fig. 35)* if necessary using the femoral head beater (available on request) *(Fig. 36)*.

Then reduce the joint after thoroughly washing the joint surfaces *(Fig. 37)*.

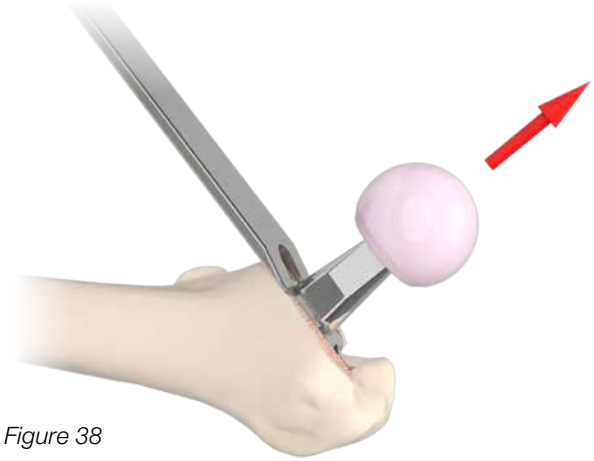


Figure 38

COMPONENTS REMOVAL

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

IMPORTANT: *If only the head needs removing and replacing with a ceramic head, always use "optional" ceramic revision heads which have a Titanium safety taper (Codes 5010.42.0xx).*

MODULAR STEM

Remove the modular neck using the neck extractor *(Fig. 38)* or by screwing the inertial beater (optional code nr. 9035.05.102) to the modular neck extractor *(Fig. 39)*.

Secure the broach handle to the stem and tap to extract the stem *(Fig. 40)*.

Figure 39

MINIMA SYSTEM SURGICAL TECHNIQUE

Components removal

Figure 40

MONOLITHIC STEM

Screw the stem positioner to the final stem. Screw the slap hammer (optional code nr. 9035.05.102) to the stem positioner and remove *(Fig. 41)*.

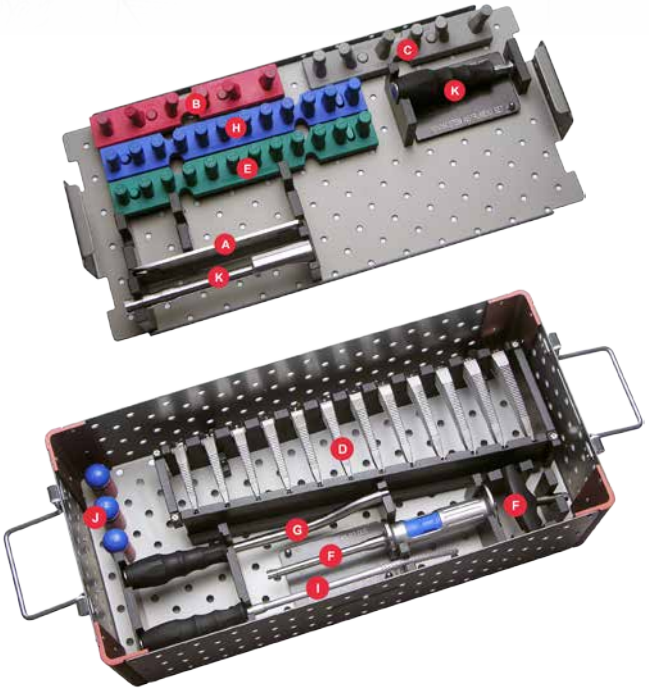
IMPORTANT: *This method may be used in cases where biological fixation is absent or weak; otherwise it may be necessary to separate the integrated surfaces of the bone using suitable scalpels.*

Figure 41

MINIMA SYSTEM SURGICAL TECHNIQUE

Instrument set

9045.03.000 Instrument set for MINIMA femoral stem

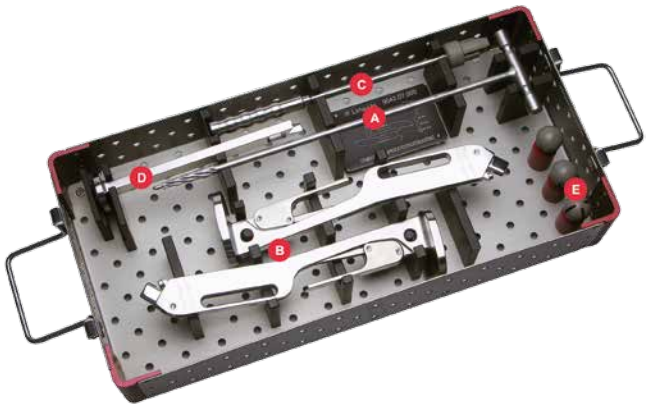


Ref.	CODE	DESCRIPTION	Qty.
A	9013.50.120	multipurpose extractor	1
B	9042.20.110	STD - S trial neck	1
B	9042.20.210	STD - AVR / RVL – S trial neck	1
B	9042.20.310	STD - AVL / RVR – S trial neck	1
B	9042.25.110	LAT – S trial neck	1
B	9042.25.210	LAT - AVR / RVL – S trial neck	1
B	9042.25.310	LAT - AVL / RVR – S trial neck	1
C	9042.20.130	STD – L trial neck	1
C	9042.20.230	STD - AVR / RVL – L trial neck	1
C	9042.20.330	STD - AVL / RVR – L trial neck	1
C	9042.25.130	LAT – L trial neck	1
C	9042.25.230	LAT - AVR / RVL – L trial neck	1
C	9042.25.330	LAT - AVL / RVR – L trial neck	1
D	9045.03.010	#1 rasp	1
D	9045.03.020	#2 rasp	1
D	9045.03.030	#3 rasp	1
D	9045.03.040	#4 rasp	1
D	9045.03.050	#5 rasp	1
D	9045.03.060	#6 rasp	1
D	9045.03.070	#7 rasp	1
D	9045.03.080	#8 rasp	1
D	9045.03.090	#9 rasp	1
D	9045.03.100	#10 rasp	1
D	9045.03.110	#11 rasp	1
D	9045.03.120	#12 rasp	1
E	9045.03.201	#1 STD trial neck	1
E	9045.03.202	#2 STD trial neck	1
E	9045.03.203	#3 STD trial neck	1
E	9045.03.204	#4 STD trial neck	1
E	9045.03.205	#5 STD trial neck	1
E	9045.03.206	#6 STD trial neck	1
E	9045.03.207	#7 STD trial neck	1
E	9045.03.208	#8 STD trial neck	1
E	9045.03.209	#9 STD trial neck	1
E	9045.03.210	#10 STD trial neck	1
E	9045.03.211	#11 STD trial neck	1
E	9045.03.212	#12 STD trial neck	1
F	9045.03.300	threaded stem inserter	1
G	9045.03.400	curved stem inserter	1
H	9045.04.201	#1 LAT trial neck	1
H	9045.04.202	#2 LAT trial neck	1
H	9045.04.203	#3 LAT trial neck	1
H	9045.04.204	#4 LAT trial neck	1
H	9045.04.205	#5 LAT trial neck	1
H	9045.04.206	#6 LAT trial neck	1
H	9045.04.207	#7 LAT trial neck	1
H	9045.04.208	#8 LAT trial neck	1
H	9045.04.209	#9 LAT trial neck	1
H	9045.04.210	#10 LAT trial neck	1
H	9045.04.211	#11 LAT trial neck	1
H	9045.04.212	#12 LAT trial neck	1
I	9095.10.162	curved rasp	1
J	9095.10.711	Dia. 28 S trial head	1
J	9095.10.712	Dia. 28 M trial head	1
J	9095.10.713	Dia. 28 L trial head	1
K	9095.11.101	modular neck extractor	1
	9045.03.950	sterilisable box	1

9042.06.000 Instrument set for antero/lateral approach

Ref.	CODE	DESCRIPTION	Qty.
A	9042.15.210	Reamer	1
B	9042.15.225	stem rasp-positioner handpiece	2
C	9042.15.230	neck beater	1
D	9095.10.160	diaphyseal canal chisel	1
E	9095.10.511	low taper trial head 12/14 Dia. 28mm S	1
E	9095.10.512	low taper trial head 12/14 Dia. 28mm M	1
E	9095.10.513	low taper trial head 12/14 Dia. 28mm L	1
	9042.06.950	sterilisable box	1

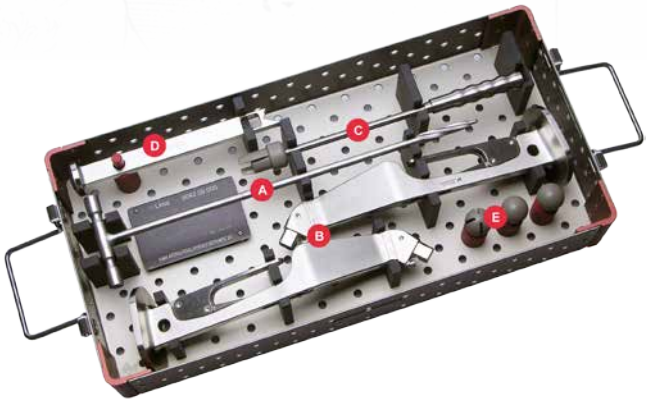
9042.07.000 Instrument set for postero-lateral/lateral approach



Ref.	CODE	DESCRIPTION	Qty.
A	9042.15.210	Reamer	1
B	9042.15.220	stem rasp-positioner handpiece	2
C	9042.15.230	neck beater	1
D	9095.10.160	diaphyseal canal chisel	1
E	9095.10.511	low taper trial head 12/14 Dia. 28mm S	1
E	9095.10.512	low taper trial head 12/14 Dia. 28mm M 28mm M	1
E	9095.10.513	low taper trial head12/14 Dia. 28mm L	1
	9042.07.950	sterilisable box	1

MINIMA SYSTEM SURGICAL TECHNIQUE
Instrument set

9042.09.000 Instrument set for direct lateral approach



Ref.	CODE	DESCRIPTION	Qty.
A	9042.15.210	Reamer	1
B	9042.15.215	Left Double Offset stem positioner rasp-handpiece	1
B	9042.15.216	Right Double Offset stem positioner rasp-handpiece	1
C	9042.15.230	neck beater	1
D	9095.10.160	diaphyseal canal chisel	1
E	9095.10.511	low taper trial head 12/14 Dia. 28mm S	1
E	9095.10.512	low taper trial head 12/14 Dia. 28mm M	1
E	9095.10.513	low taper trial head 12/14 Dia. 28mm L	1
	9042.09.950	sterilisable box	1

ADDITIONAL INSTRUMENTS

Ref.	CODE	DESCRIPTION	Qty.
■	9035.05.152	stem extractor	1

■ Upon request

Product codes

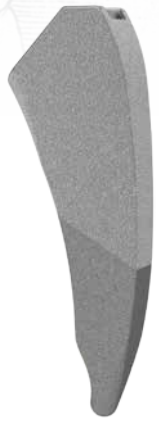
MINIMA S - STANDARD MONOLITHIC STEM

Ti6Al4V + PoroTi	4503.21.010	#1
	4503.21.020	#2
	4503.21.030	#3
	4503.21.040	#4
	4503.21.050	#5
	4503.21.060	#6
	4503.21.070	#7
	4503.21.080	#8
	4503.21.090	#9
	4503.21.100	#10
	4503.21.110	#11
	4503.21.120	#12

MINIMA S - LATERALIZED MONOLITHIC STEM (OFFSET +5 MM)

Ti6Al4V + PoroTi	4504.21.010	#1
	4504.21.020	#2
	4504.21.030	#3
	4504.21.040	#4
	4504.21.050	#5
	4504.21.060	#6
	4504.21.070	#7
	4504.21.080	#8
	4504.21.090	#9
	4504.21.100	#10
	4504.21.110	#11
	4504.21.120	#12

MINIMA SYSTEM SURGICAL TECHNIQUE
Product codes



MINIMA M - MODULAR STEM

Ti6Al4V + PoroTi	4502.21.010	#1
	4502.21.020	#2
	4502.21.030	#3
	4502.21.040	#4
	4502.21.050	#5
	4502.21.060	#6
	4502.21.070	#7
	4502.21.080	#8
	4502.21.090	#9
	4502.21.100	#10
	4502.21.110	#11
	4502.21.120	#12

MODULAR NECKS - TAPER 12/14

CoCrMo		Modular necks
	4220.09.110	STD-S (S1)
	4220.09.130	STD-L (L1)
	4220.09.210	AVR/RVL-S (S2)
	4220.09.230	AVR/RVL-L (L2)
	4220.09.310	AVL/RVR-S (S3)
	4220.09.330	AVL/RVR-L (L3)
		Lateralizing modular necks
	4225.09.110	LAT-S (S4)
	4225.09.130	LAT-L (L4)
	4225.09.210	LAT-AVR/RVL-S (S5)
	4225.09.230	LAT-AVR/RVL-L (L5)
	4225.09.310	LAT-AVL/RVR-S (S6)
	4225.09.330	LAT-AVL/RVR-L (L6)

** IMPORTANT: . For allergic patients, modular necks in Titanium Ti6Al4V may be used, code numbers 4220.12.xxx and, in the lateralizing version, code numbers 4225.15.xxx.*

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