H-MAX SYSTEM

Restoring Motion

SURGICAL TECHNIQUE

Lima Corporate
Orthopaedic motion

H-MAX SYSTEM SURGICAL TECHNIQUE

Index

Limacorporate S.p.A. is a manufacturer of prosthetic implants and as such dœs not perform medical procedures. This documentation concerning surgical techniques, which provides surgeons with general guidelines for implanting the H-MAX 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. For further information about our products, please visit our web site at www.limacorporate.com

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

H-MAX SYSTEM SURGICAL TECHNIQUE
Indications, Contraindications and Warnings

INDICATIONS

H-MAX stems are indicated for use in partial or total hip arthroplasty and they are intended for press-fit (uncemented) use. When used in total hip arthroplasty, monolithic cementless stems are intended for use with modular heads and compatible acetabular cups. When used in partial hip arthroplasty, they are intended for use with femoral heads intended for partial hip arthroplasty or bipolar heads.
Hip arthroplasty is intended for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

- non-inflammatory degenerative joint disease including osteoarthritis, avascular necrosis and dysplasia;
- rheumatoid arthritis;
- treatment of femoral head and neck fractures;
- revisions in cases of good remaining femoral bone stock.

H-MAX M femoral stems are indicated also for correction of functional deformities.

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 or extended previous revision surgery) 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.

H-MAX M femoral stems are contraindicated also for patients with renal impairment (CoCrMo).

RISK FACTORS

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

- overweight;
- strenuous physical activities (active sports, heavy physical work);
- fretting of 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 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

WARNINGS

The surgeon should carefully plan the surgery considering the following:

1. Small sized stems: the Small sized stems are designed for patients with a small Intramedullary canal and/or metaphyseal region of the femur. The reduced size (M/L width) of these stems results in a corresponding reduction in the fatigue strength of the implant;
2. High Offset combinations (use of lateralized stems): the lateralized stems are designed to restore the functional offset of the hip joint to be comparable to that of the contralateral hip, however greater neck lengths are accompanied by a higher risk of failure (e.g. breakage due to fatigue). Complications or failures of the total hip replacement are more likely to 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 (BMI >25 kg/m2) and/or have high activity levels and/or poor bone quality may not be candidates for a modular hip replacement with H-MAX M femoral stems.

COMBINATIONS ALLOWED/NOT ALLOWED

Allowed combinations between Femoral head and H-MAX M Modular necks:

- With the exception of Lateralizing Long Modular necks (#LAT-L), the modular necks can be coupled only with S, M, L and XL femoral heads;
- Lateralizing Long Modular necks (#LAT-L) can be coupled only with S, M and L femoral heads. Use of femoral heads with greater neck lengths may result in failure of the hip stem (e.g. breakage due to fatigue). The use of Ti6Al4V Modular necks is allowed only in patients allergic to CoCrMo.

STEM SIZES

H-MAX S and H-MAX C are manufactured in 11 sizes for the two versions standard and lateralizing. The H-MAX M is available in 10 different sizes. The CCD in the standard version is 134°; the CCD in the lateralizing version is 131°.

The dimension of the stems grows harmonically with size; in the frontal view the increase in width is 1 mm for each size. In the lateral view the thickness increases of 0.5 mm for each size.

HORIZONTAL OFFSET TABLE FOR H-MAX S AND H-MAX C - 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

HORIZONTAL OFFSET TABLE FOR H-MAX 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

Figure 1
RX with H-MAX S template

Figure 2
RX with H-MAX M template

PRE-OPERATIVE PLANNING

To obtain the best results, preoperative planning is recommended with the use of templates (showing a 15% enlarged image of the profiles).

Use good quality frontal and axial view radiographs with adequate contrast that are large enough to contain the entire length of the pre-op template stems *(Figs. 1-2)*.

Digital templates compatible with most surgical planning software are also available.

STEM SIZE SELECTION

To find the right stem size the contour lines of the proximal part should fill the femoral epiphyseal region.
Make sure that the stem does not interfere with the femoral curvature along the axial projection.

It is important to consider that the fixation of the stem is obtained in the proximal part, therefore, the filling of the canal is not required in the distal part.
Identify the size and type of neck to restore the correct centre of rotation, checking the anteversion level in the sagittal plane.

Identify the neck resection level by making the apex of the greater trochanter coincide with the centre of the medium femoral head.

H-MAX S and C templates indicate the centre of rotation in the two versions for the different lengths of the heads *(Figs. 3-4)*.

H-MAX M templates indicate the centre of rotation for the different versions of the necks (standard short, standard-long, lateralizing short, lateralizing-long) and for the different heads lenghts *(Fig. 5)*.

H-MAX M templates also indicate the centre of rotation for the versions standard-short and standard-long in the axial projection *(Fig. 6)*.

Note. *Pre-operative planning provides useful indications for the use of the the implant but does not definitely extabilish the size of the stem to be used, which must be verified during the surgery.*

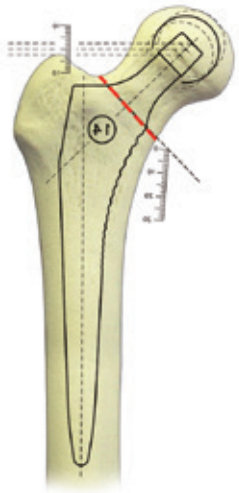


Figure 3
H-MAX S Standard

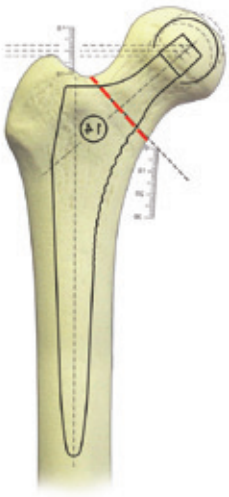


Figure 4
H-MAX S Lateralizing

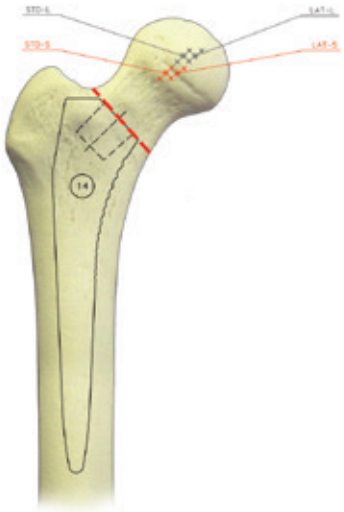


Figure 5
H-MAX M

Figure 6
H-MAX M

Neck resection

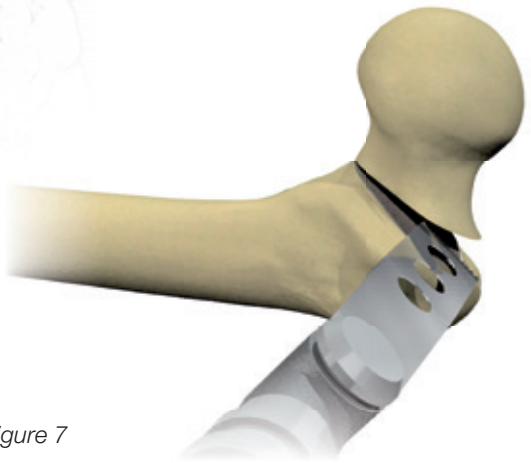


Figure 7

NECK RESECTION

After having dislocated the femur, the femoral head is resected *(Fig. 7)*.

FEMUR PREPARATION

Figure 8

Start preparing the canal with the box chisel, which allows to open the greater trochanter area *(Fig. 8)*.

The canal is then opened using a reamer *(Fig. 9)*.

Figure 9

The H-MAX instrument set consists of a series of broaches *(Fig. 10)*; the broaches are connected to the broach handles.

Figure 10

H-MAX SYSTEM SURGICAL TECHNIQUE

Femur preparation

Broach handles are available in the following versions: “straight”, ‘’straight for Direct Anterior Approach “single offset”, and “double offset” fitting to different surgical approaches *(Fig. 11a, b, c, d)*.

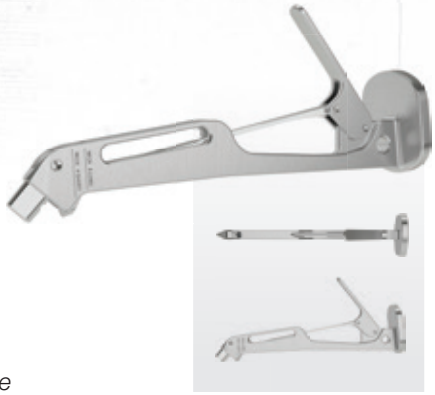


Figure 11a
Straight Handle

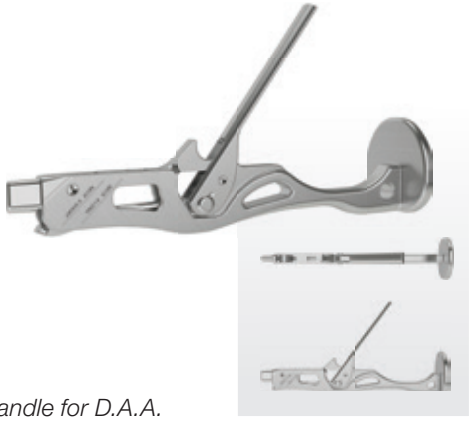


Figure 11b
Straight Handle for D.A.A.

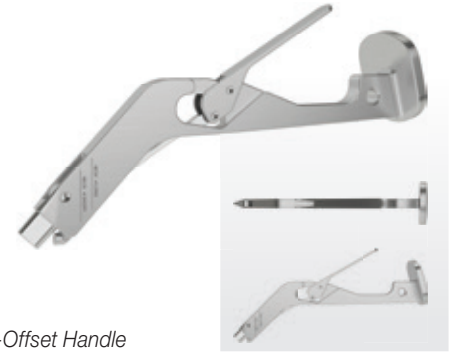


Figure 11c
Curved Single-Offset Handle

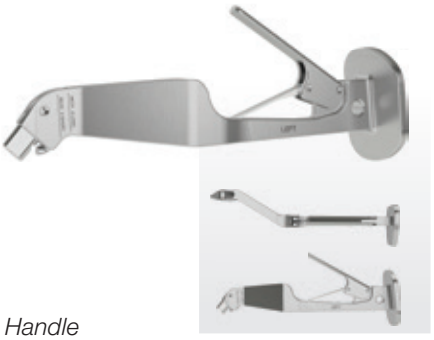


Figure 11d
Double Offset Handle

Figure 12

Connect the broach to the handle by lifting the lever and inserting the broach with its medial part oriented towards the lever *(Fig. 12)*.

Tighten the lever until it is fully closed *(Fig. 13)*.

Start broaching the canal using the smallest broach, maintaining the correct anteversion (approx. 15°).
Insert the broach untill the tilted plane of the broach coincides with the resection line of the neck.

Figure 13

Note. *Trial reduction with broach #08 can be done for H-MAX S and H-MAX C stems only (H-MAX M stem smallest size is #09).*

H-MAX SYSTEM SURGICAL TECHNIQUE

Femur preparation

Figure 14a

Figure 14b

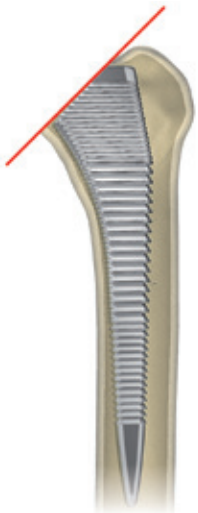


Figure 14c

Note. *The resection line is defined during the Pre operative planning with the use of templates.*

If the resection line results to be different from the planning this difference has to be taken into account (Fig. 14 a, b, c).

Proceed with the next size up broach and continue until the epiphyseal seat is filled properly.
Once the best broach size has been achieved (which may not necessarily be the one planned during the preoperative planning), remove the handle and leave the broach in situ (Fig. 14b).

Figure 15

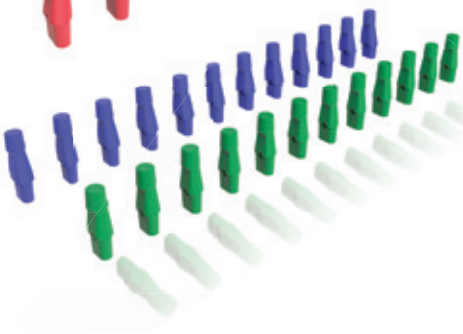


Figure 16

TRIAL REDUCTION

In case the acetabular component is implanted before the femoral stem, a trial reduction can be performed.
The H-MAX M instrument set includes the trials of the 12 modular necks short (red) and long (grey) *(Fig. 15)*.

The H-MAX S and C the instrument set includes the trials for the necks in the two versions; standard (green) and lateralizing (blue) for each size *(Fig. 16)*.

Insert the required trial neck with the neck positioner *(Fig. 17)*.

Insert the trial head *(Fig. 18)* and perform the trial reduction *(Fig. 19)*.

Remove the trial neck using the neck extractor.

Figure 17

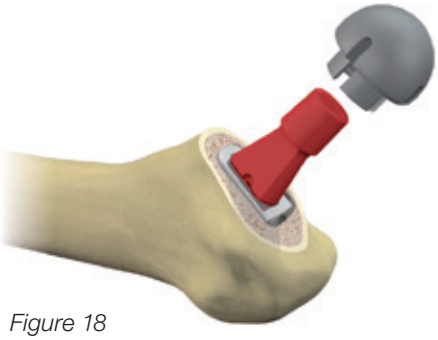


Figure 18

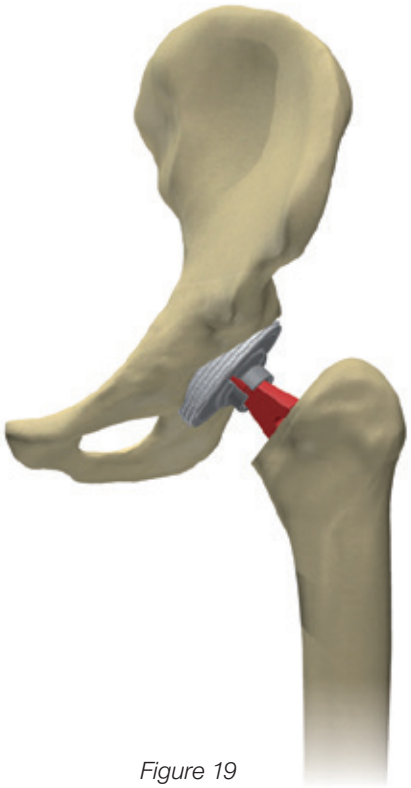


Figure 19

Definitive Stem Insertion H-MAX S

Figure 21

Figure 20

DEFINITIVE STEM INSERTION H-MAX S

The stem can be implanted using a screwed positioned (A) or a free-hand impactor (B).

(A) Take the H-MAX S stem out of the box with the size corresponding to the last broach used and remove it from its sterile packaging. Screw the stem positioner on the definitive stem *(Fig. 20)*.

The washer indicates the locking/ unlocking direction *(Fig. 21)*. The T Wrench, inserted in the stem positioner, it is useful to lock up the stem to the stem positioner *(Fig. 22)*. After removing the T wrench it is possible to insert the stem by impacting on the stem positioner.
The line of separation between the polished finishing and the HA coating corresponds to the level reached by the last broach used *(Fig. 23)*.

Figure 22

(B) Manually insert the stem into the femoral cavity, align the free-hand impactor (available on request ref. 9095.11.111) on the lateral side of the stem *(Fig. 24)* and impact until fully inserted.

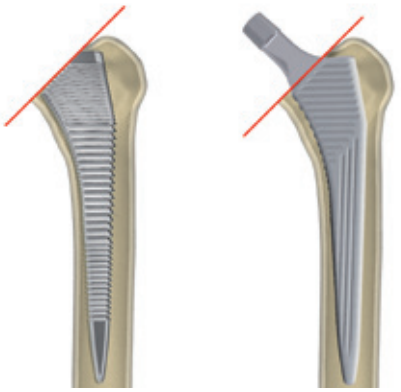


Figure 23

Figure 24

Figure 25

DEFINITIVE STEM INSERTION H-MAX M

Take the H-MAX M stem out of the box with the size corresponding to the last broach used and remove it from its sterile packaging *(Fig. 25)*.

Using the broach handle, impact the stem, until the tilted plane of the stem reaches the level of the broach *(Figs. 26a, b, c)*.

The neck can be further checked by inserting the trial neck on the final stem. Clean and dry the conical taper of the stem. Take the definitive neck from the sterile packaging and impact it with the neck positioner *(Fig. 27)* impacting it on its axis.

Figure 26a

Figure 26b

Figure 27

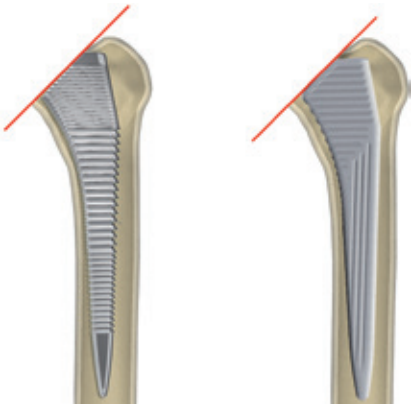


Figure 26c

Definitive Stem Insertion H-MAX C

Figure 28

Figure 29

DEFINITIVE STEM INSERTION H-MAX C

After inserting the distal plug fill the femoral canal with acrylic cement from distal to proximal. Proceed with the introduction of the stem as for the H-MAX S as follows.

Please look at the LIMA-CMT 1, 2 and G brochure for indication of the distal plug positioning and the cementing procedure.

Figure 30

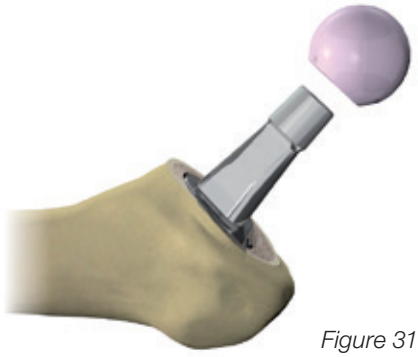


Figure 31

Figure 32

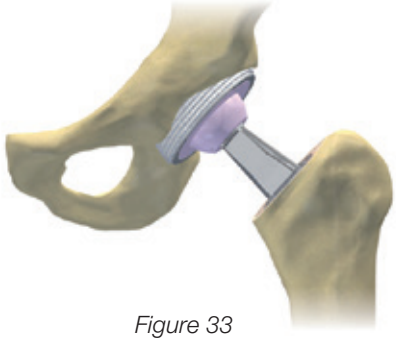


Figure 33

DEFINITIVE HEAD INSERTION

Once the correct head size, diameter and material have been chosein, the length of the head can be rechecked using the trial heads. Take a head with the determined diameter and length from its sterile packaging *(Fig. 30)*.

Carefully clean and dry the neck taper, this is essential when using ceramic heads, fix the head by pressing it in and rotating it along the neck axis *(Fig. 31)*.

Remove the protective cap and tap slightly along the cone axis using the femoral head beater (available upon request) *(Fig. 32)*.

After having cleaned the articular surfaces, reduce the articulation *(Fig. 33)*.

Note. *For H-MAX M, with all "long" version necks, the use of XL, XXL, XXXL head lenghts is not allowed.*

Components removal

Figure 34

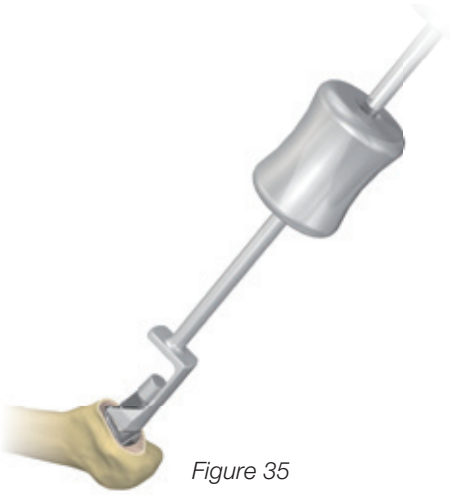


Figure 35

COMPONENTS REMOVAL

If necessary, the prosthetic components can be removed. To remove the femoral head, simply tap the bottom of the head in the axial direction using a beater.

Note. *If only the head needs to be replaced, never use a ceramic head on the same cone.*

H-MAX S / H-MAX C

Screw the stem positioner on the stem. Screw the stem extractor on the stem positioner and use the inertial beater to extract the stem *(Fig. 34)*.

H-MAX M

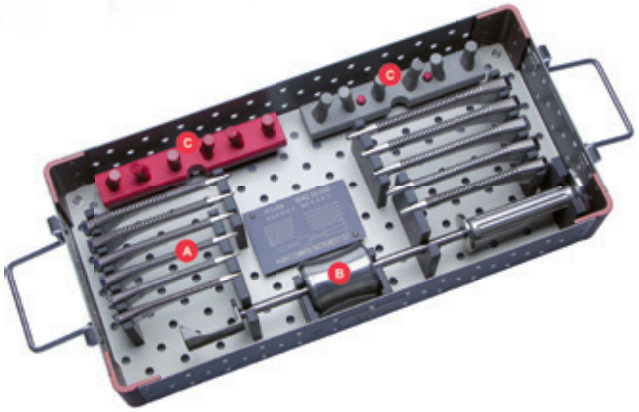
Remove the modular neck with the neck extractor *(Fig. 35)*. Lock the broach handle on the broach and beat backward to extract the stem.

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.*

H-MAX SYSTEM SURGICAL TECHNIQUE

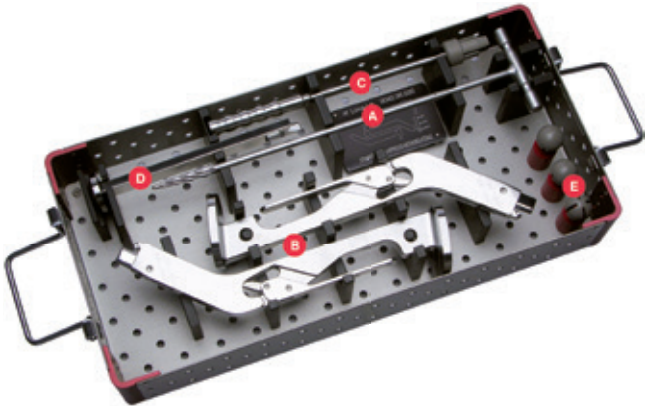
Instrument Set

9042.05.000 H-MAX Common Instrument Set



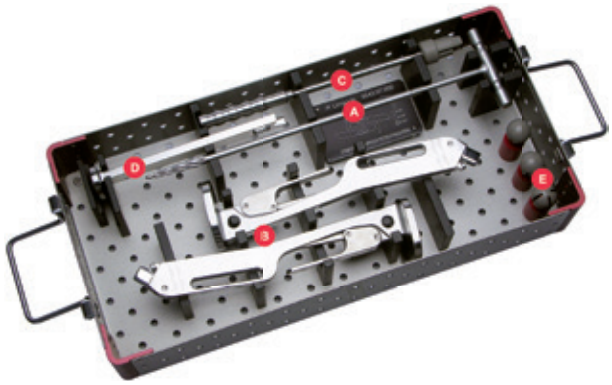
Ref.	CODE	DESCRIPTION	Qty.
A	9042.05.080	Broach #08	1
A	9042.05.090	Broach #09	1
A	9042.05.100	Broach #10	1
A	9042.05.110	Broach #11	1
A	9042.05.120	Broach #12	1
A	9042.05.130	Broach #13	1
A	9042.05.140	Broach #14	1
A	9042.05.150	Broach #15	1
A	9042.05.160	Broach #16	1
A	9042.05.170	Broach #17	1
A	9042.05.180	Broach #18	1
B	9042.15.240	Neck Extractor	1
C	9042.20.110	Trial Neck STD - S	1
C	9042.20.130	Trial Neck STD - L	1
C	9042.20.210	Trial Neck STD - AVR / RVL - S	1
C	9042.20.230	Trial Neck STD - AVR / RVL - L	1
C	9042.20.310	Trial Neck STD - AVL / RVR - S	1
C	9042.20.330	Trial Neck STD - AVL / RVR - L	1
C	9042.25.110	Trial Neck LAT - S	1
C	9042.25.130	Trial Neck LAT - L	1
C	9042.25.210	Trial Neck LAT - AVR / RVL - S	1
C	9042.25.230	Trial Neck LAT - AVR / RVL - L	1
C	9042.25.310	Trial Neck LAT - AVL / RVR - S	1
C	9042.25.330	Trial Neck LAT - AVL / RVR - L	1
	9042.05.950	Sterilizable Box	1

9042.06.000 H-MAX Anterior/Lateral Approach Instrument Set



Ref.	CODE	DESCRIPTION	Qty.
A	9042.15.210	Reamer	1
B	9042.15.225	Broach Handle-Stem Positioner	2
C	9042.15.230	Neck Impactor	1
D	9095.10.160	Canal Chisel	1
E	9095.10.511	Trial Head Low Taper 12/14 Dia. 28mm S	1
E	9095.10.512	Trial Head Low Taper 12/14 Dia. 28mm M	1
E	9095.10.513	Trial Head Low Taper 12/14 Dia. 28mm L	1
	9042.06.950	Sterilizable Box	1

9042.07.000 H-MAX Posterolateral/Lateral Approach Instrument Set

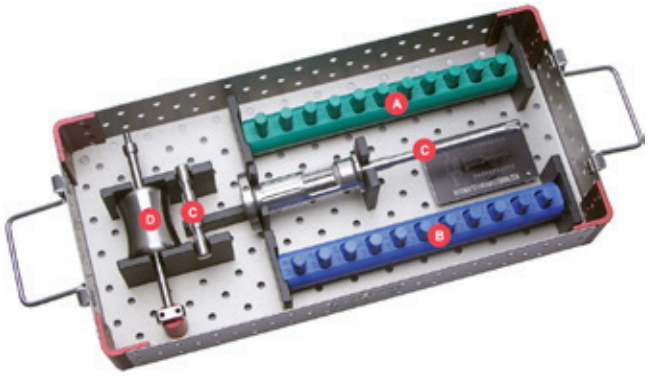


Ref.	CODE	DESCRIPTION	Qty.
A	9042.15.210	Reamer	1
B	9042.15.220	Straight Broach Handle-Stem Positioner	2
C	9042.15.230	Neck Impactor	1
D	9095.10.160	Canal Chisel	1
E	9095.10.511	Trial Head Low Taper 12/14 Dia. 28mm S	1
E	9095.10.512	Trial Head Low Taper 12/14 Dia. 28mm M	1
E	9095.10.513	Trial Head Low Taper 12/14 Dia. 28mm	1
	9042.07.950	Sterilizable Box	1

H-MAX SYSTEM SURGICAL TECHNIQUE

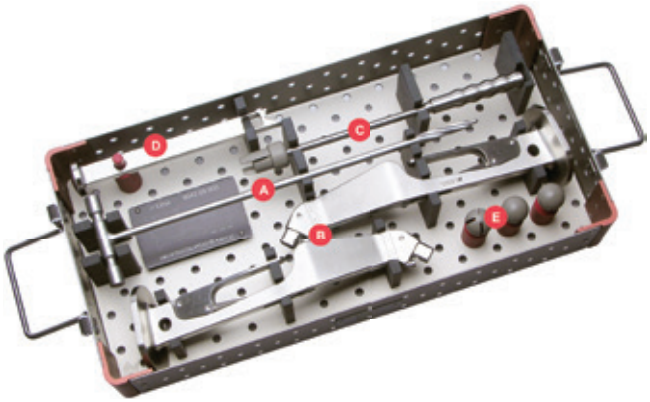
Instrument set

9042.08.000 Instrument Set for H-MAX S Femoral Stem



Ref.	CODE	DESCRIPTION	Qty.
A	9042.50.080	Trial Modular Neck #8	1
A	9042.50.090	Trial Modular Neck #9	1
A	9042.50.100	Trial Modular Neck #10	1
A	9042.50.110	Trial Modular Neck #11	1
A	9042.50.120	Trial Modular Neck #12	1
A	9042.50.130	Trial Modular Neck #13	1
A	9042.50.140	Trial Modular Neck #14	1
A	9042.50.150	Trial Modular Neck #15	1
A	9042.50.160	Trial Modular Neck #16	1
A	9042.50.170	Trial Modular Neck #17	1
A	9042.50.180	Trial Modular Neck #18	1
B	9042.51.080	Trial Lateralized Modular Neck #8	1
B	9042.51.090	Trial Lateralized Modular Neck #9	1
B	9042.51.100	Trial Lateralized Modular Neck #10	1
B	9042.51.110	Trial Lateralized Modular Neck #11	1
B	9042.51.120	Trial Lateralized Modular Neck #12	1
B	9042.51.130	Trial Lateralized Modular Neck #13	1
B	9042.51.140	Trial Lateralized Modular Neck #14	1
B	9042.51.150	Trial Lateralized Modular Neck #15	1
B	9042.51.160	Trial Lateralized Modular Neck #16	1
B	9042.51.170	Trial Lateralized Modular Neck #17	1
B	9042.51.180	Trial Lateralized Modular Neck #18	1
C	9046.10.230	Stem Positioner	1
D	9046.10.235	Stem Extractor	1
	9042.08.920	Sterilizable box	1

9042.09.000 H-MAX Anterolateral Approach Instrument Set



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 Impactor	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	Sterilizable box	1

9095.11.112 Straight handle for D.A.A.

	CODE	DESCRIPTION
■	9095.11.112	Straight handle for D.A.A

■ upon request

9095.11.111 Free-hand impactor

	CODE	DESCRIPTION
■	9095.11.111	Free-hand impactor

■ upon request

H-MAX SYSTEM SURGICAL TECHNIQUE
Product codes

H-MAX S - STANDARD STEMS - TAPER 12/14

Ti6Al4V + HA	■ 4250.20.080	# 8
	4250.20.090	# 9
	4250.20.100	# 10
	4250.20.110	# 11
	4250.20.120	# 12
	4250.20.130	# 13
	4250.20.140	# 14
	4250.20.150	# 15
	4250.20.160	# 16
	4250.20.170	# 17
	4250.20.180	# 18

■ upon request

H-MAX S - LATERALIZING STEMS (OFFSET +5MM) - TAPER 12/14

Ti6Al4V + HA	■ 4251.20.080	# 8
	4251.20.090	# 9
	4251.20.100	# 10
	4251.20.110	# 11
	4251.20.120	# 12
	4251.20.130	# 13
	4251.20.140	# 14
	4251.20.150	# 15
	4251.20.160	# 16
	4251.20.170	# 17
	4251.20.180	# 18

■ upon request

Product codes

H-MAX M - MODULAR STEMS

Ti6Al4V + HA	4205.20.090	# 9
	4205.20.100	# 10
	4205.20.110	# 11
	4205.20.120	# 12
	4205.20.130	# 13
	4205.20.140	# 14
	4205.20.150	# 15
	4205.20.160	# 16
	4205.20.170	# 17
	4205.20.180	# 18

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.*

H-MAX SYSTEM SURGICAL TECHNIQUE

Product codes

H-MAX C - STANDARD STEMS - TAPER 12/14

FeCrNiMnMoNbN	4260.07.080	# 8
	4260.07.090	# 9
	4260.07.100	# 10
	4260.07.110	# 11
	4260.07.120	# 12
	4260.07.130	# 13
	4260.07.140	# 14
	4260.07.150	# 15
	4260.07.160	# 16
	4260.07.170	# 17
	4260.07.180	# 18

H-MAX C - LATERALIZING STEMS - TAPER 12/14

FeCrNiMnMoNbN	4261.07.080	# 8
	4261.07.090	# 9
	4261.07.100	# 10
	4261.07.110	# 11
	4261.07.120	# 12
	4261.07.130	# 13
	4261.07.140	# 14
	4261.07.150	# 15
	4261.07.160	# 16
	4261.07.170	# 17
	4261.07.180	# 18

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