LINK®

MEGASYSTEM-C®

Assembling Instruments

Assembling & Application

Presented by:

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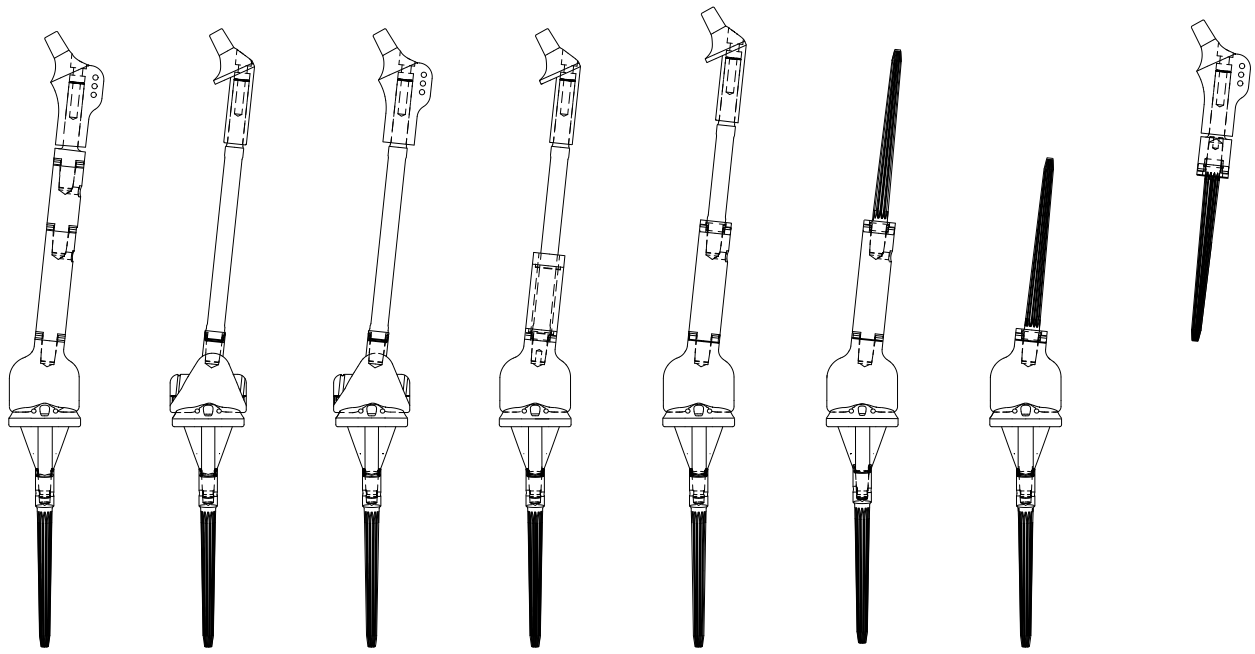
MEGASYSTEM-C®
Assembling Instruments

The life expectancy and performance of modular implants used in arthroplasty and tumour surgery rely on the integrity and strength of the morse taper connections between the various components. These connections are key to the longevity, performance and outcome of the surgical procedure.

Regardless of the precision and quality of craftsmanship of the male and female taper geometries and surface parameters, the way in which the mechanical connection is ultimately made is of central importance. Internal and independent studies* have shown that the strongest blow struck to engage the connection components taper determines the strength necessary to disengage the taper connection. Further strikes of equal or unequal force increase such strength only marginally. Furthermore, taper surfaces must be dry and clean prior to assembly. Wet surfaces bring about unpredictable changes in the connection strength. Axial alignment of the taper pair, the correct size mallet and a solid, non-re-silient assembling table are essential to ensure the best possible connection between components.

The design features of **LINK® MEGASYSTEM-C® assembling instruments** meet the requirements for creating a secure, safe, and therefore permanent taper connection. It is imperative to use this instrument set to obtain repro-ducible results in taper assembly. Whenever the surgical procedure permits, the components should be assembled with the aid of the assembling table.

* *Morse-Type Tapers, Andrew T. Pennock et al.,The Journal of Arthroplasty: Vol. 17, No. 6, 2002*



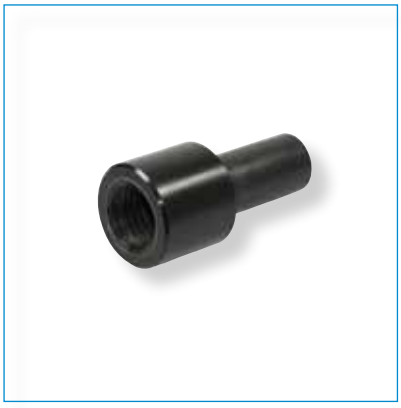
16-0118/01

Assembling Table: Superior Component

16-0118/02

Assembling Table: Inferior Component

with fixed base plate



16-0118/03

Assembling table: Silence

16-0110/01
Femur Assembling Plate

16-0110/02
Tibia Assembling Plate
for Endo-Model® SL® Knee Prostheses

16-0110/03
Tibia Assembling Plate
for Endo-Model® Knee Prostheses

16-0111/01
Assembling Protector for female taper

16-0111/02
Assembling Protector for male taper

Assembling Protectors
16-0112/01 for modular stem, size 1
16-0112/02 for modular stem, size 2
16-0112/03 for modular stem, size 3

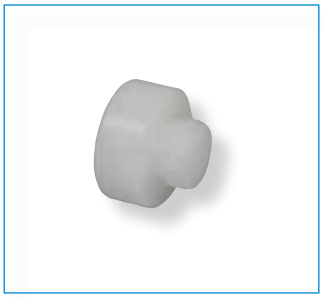
16-0113/01
Metal Core for assembling protector,
for modular stem (size 1-3)

16-0114/01
Femur Assembling Protector,
complete

16-0114/02
Block, spare part,
for femur assembling protector
16-0114/01

16-0114/03
Plate, spare part,
for femur assembling protector
16-0114/01

16-0115/01
Mallet, non-resilient proof,
800g



16-0115/02

Spare Mallet Head,

plastic, for 16-0115/01

16-0116/02

Hex Screwdriver,

Ø 5 mm

Mounting the Assembling Table

The assembling table is mounted before the operation as illustrated below.

The superior component 16-0118/01 and the silencer 16-0118/03 are assembled in sterile condition. The inferior component 16-0118/02 with fixed base plate may be kept non-sterile.

The silencer is screwed onto the inferior component.

The superior component is attached.

In use of the assembling table, place foot on base plate to prevent the table from toppling over. The table is dismantled in reverse order.

Connecting Modular Stems to Modular Femoral and Tibial Components

The femur assembling plate 16-0110/01 is placed into the reception of the superior component of the assembling table 16-0118/01.

According to the chosen size of modular stem, the metal core 16-0113/01 is screwed into assembling protector modular stem, size 1-3 (16-0112/01-03).

Prosthesis stem and femoral joint component are connected by hand (the taper surfaces must be clean and dry) and, observing the 6° valgus alignment of the femoral implant, placed on the assembling plate so that the prosthesis stem is vertical. If not, the implant assembly must be rotated 180°.

As shown in the picture, the components are struck with two powerful blows of the non-resilient mallet 16-0115/01 in order to firmly engage the taper connection (the second blow is a safety measure). The metal face of the mallet must only be used.

When using modular tibial implants, the tibial assembling plate 16-0110/02 or /03 is first placed into the reception of the superior table component.

Proceed according to the assembly of modular femoral implant. Before using the locking screws, the taper connections must be connected firmly as described, using the assembling instruments.

Connecting Stem Elements

The assembling protector for female taper 16-0111/01 is placed into the reception of the assembling table superior component.

Attaching the selected stem element.

Attaching the stem element to be connected and the assembling protector for male taper 16-0111/02.

Assemble the elements with two blows of the non-resilient mallet, using the metal face of the mallet only.

Use and Mounting of the Femur Assembling Protector

Use

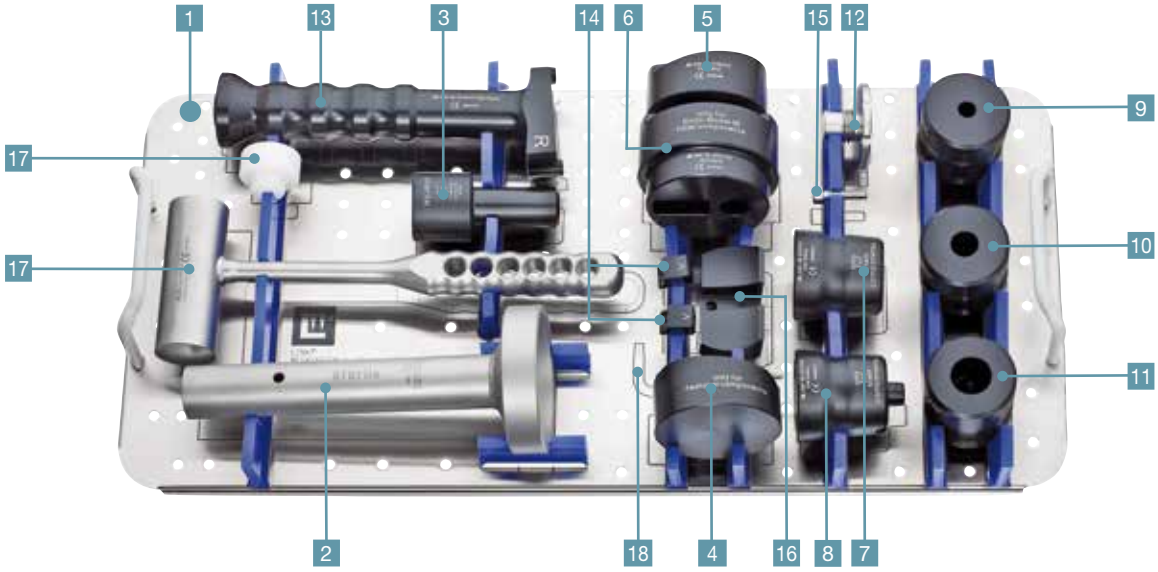
The femur assembling protector is always used if the surgical procedure does not permit assembly of implant components outside the operating field (e.g. connecting femoral joint components to push-through stems). The instrument compensates for the valgus geometry of the knee implant and permits the engagement of the tapers in axial alignment in the transverse and sagittal plane.

Its use enables taper engagement in axial alignment.

Assembly

The femur assembling protector is mounted as shown in below illustration. First the plate is connected to the handle so that, depending on the side being operated on, the letters “R” for the right side or the letters “L” for the left side are lined up. In the illustration the right side is choosen. Consecutively the block for assembling protector is secured using the hex screwdriver. The two arrows (of bock and plate) must point toward each other.

LINK® MEGASYSTEM-C® Assembling Instruments



	16-0100/00	**Instrument Set, complete** consisting of
	05-2002/03	**N21 standard container,** 575 x 275 x 130 mm
1	16-0100/01	**Tray,** empty, 550 x 265 x 50 mm
2	16-0118/01	**Assembling Table: upper part**
3	16-0118/03	**Assembling Table: silencer**
4	16-0110/01	**Femur Assembling Plate**
5	16-0110/02	**Tibia Assembling Plate** for Endo-Model® SL® knee prosthesis
6	16-0110/03	**Tibia Assembling Plate** for Endo-Model® knee prosthesis
7	16-0111/01	**Assembling Protector** for female taper
8	16-0111/02	**Assembling Protector** for male taper
		Assembling Protectors
9	16-0112/01	Size 1
10	16-0112/02	Size 2
11	16-0112/03	Size 3
12	16-0113/01	**Metal Core** for assembling protector, for modular stem (size 1-3)
13	16-0114/01	**Handle** for femur assembling protector
14	16-0114/02	**Block,** spare part for femur assembling protector 16-0114/01 (2 ea. included)
15	16-0114/04	**Screw** for assembling protectors femur
16	16-0114/03	**Plate,** spare part for femur assembling protector 16-0114/01
17	16-0115/01	**Mallet,** non-resilient, 800g, complete
18	16-0116/02	**Hex Screwdriver,** hex 5 mm

Please note the following regarding the use of our implants:

1. Choosing the right implant is very important.
The size and shape of the human bone determines the size and shape of the implant and also limits the load capacity. Implants are not designed to withstand unlimited physical stress. Demands should not exceed normal functional loads.

2. Correct handling of the implant is very important.
Under no circumstances should the shape of a finished implant be altered, as this shortens its life span. Our implants must not be combined with implants from other manufacturers.

The instruments indicated in the Surgical Technique must be used to ensure safe implantation of the components.

3. Implants must not be reused.
Implants are supplied sterile and are intended for single use only. Used implants must not be used again.

4. After-treatment is also very important.
The patient must be informed of the limitations of the implant. The load capacity of an implant cannot compare with that of healthy bone!

5. Unless otherwise indicated, implants are supplied in sterile packaging.
Note the following conditions for storage of packaged implants:
- Avoid extreme or sudden changes in temperature.
- Sterile implants in their original, intact protective packaging may be stored in permanent buildings up until the “Use by” date indicated on the packaging.
- They must not be exposed to frost, dampness or direct sunlight, or mechanical damage.
- Implants may be stored in their original packaging for up to 5 years after the date of manufacture. The “Use by” date is indicated on the product label.
- Do not use an implant if the packaging is damaged.

6. Traceability is important.
Please use the documentation stickers provided to ensure traceability.

7. Further information on the material composition is available on request from the manufacturer.

Follow the instructions for use!

Waldemar Link GmbH & Co. KG, Hamburg, Germany

The Surgical Technique described has been written to the best of our knowledge and belief, but it does not relieve the surgeon of his/her responsibility to duly consider the particularities of each individual case.

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