



OsteoBridge™ Knee Arthrodesis



**Surgical technique and
ordering information**

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Description

The OsteoBridge™ Knee Arthrodesis System serves as an implant to fuse the knee joint. The implant can also be used for bridging large bone defects and the resection of the metaphysis zone of femur and tibia.

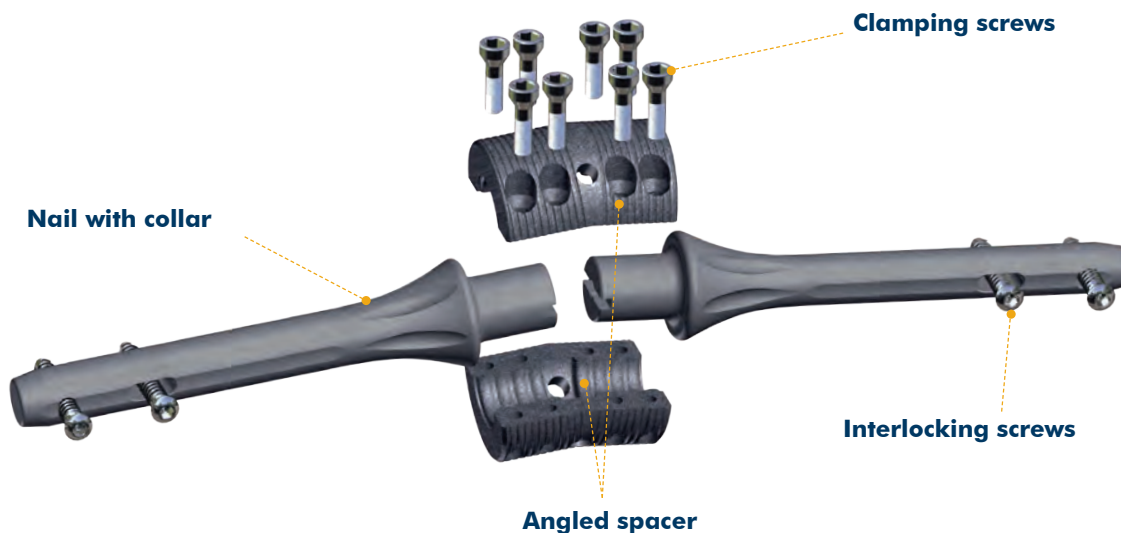
The System is available in three versions:

I. Standard System – Basic treatment

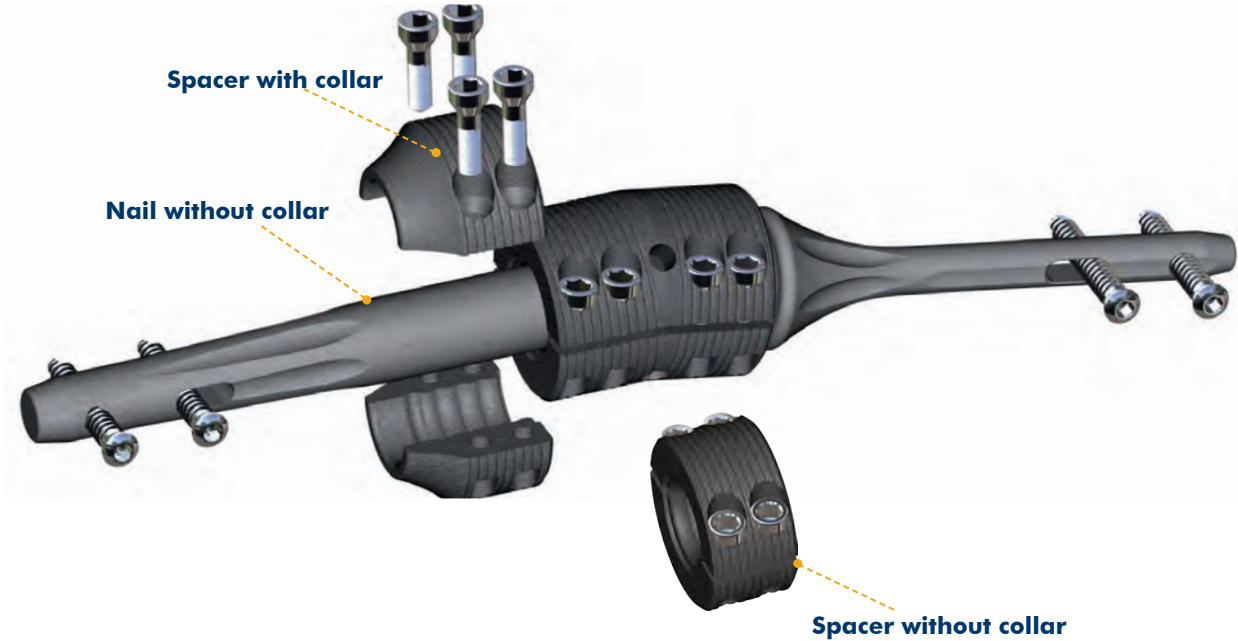
II. Extended System – Flexible treatment

III. Extended System PLUS – Complete treatment

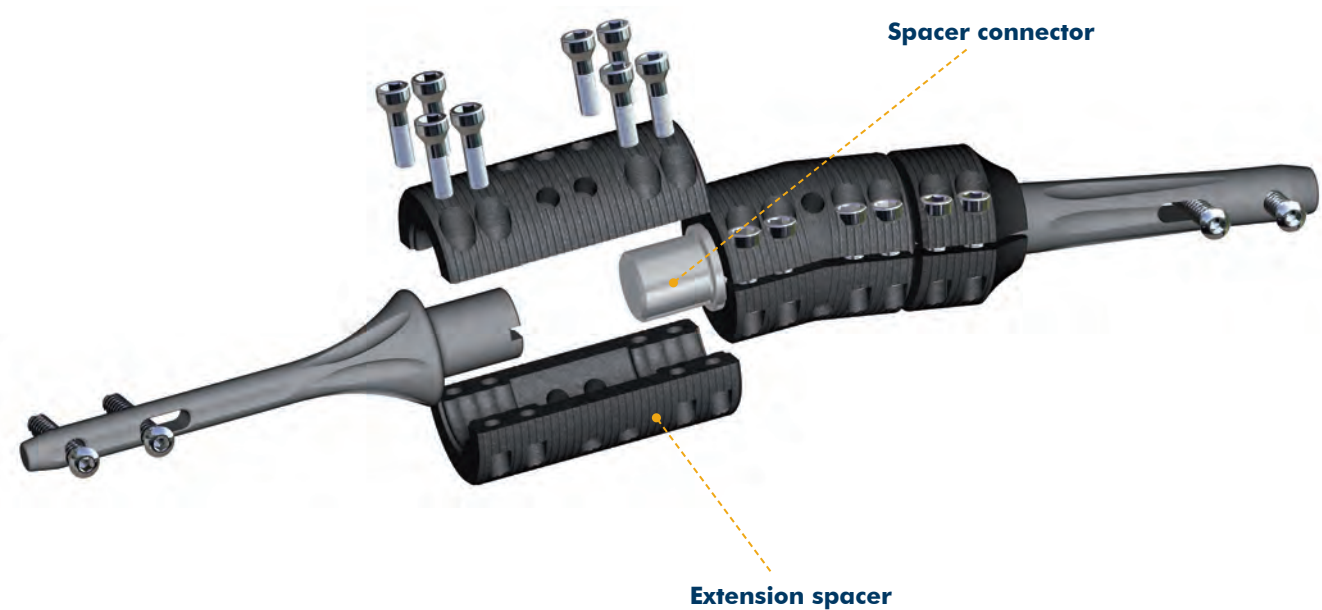
I. Standard System: The Standard System consists of an angled spacer for bridging the damaged joint as well as nails with a collar in different lengths and diameters to anchor the implant in the femur and tibia. The nails are trumpet-shaped to optimize their stability in the damaged bone. An adjustment of the valgus or varus positioning of the joint can be archived by rotation of the angled spacer.



II. Extended System: The Extended System contains additional tapered and ribbed nails without collar. Spacers with a length of 20 mm without a collar and 30 mm with collar can be clamped onto these nails.



III. Extended System PLUS: Spacers in the lengths from 40 mm up to 70 mm to bridge particularly large bone defects are part of the Extended System PLUS. They have to be connected with a spacer connector.

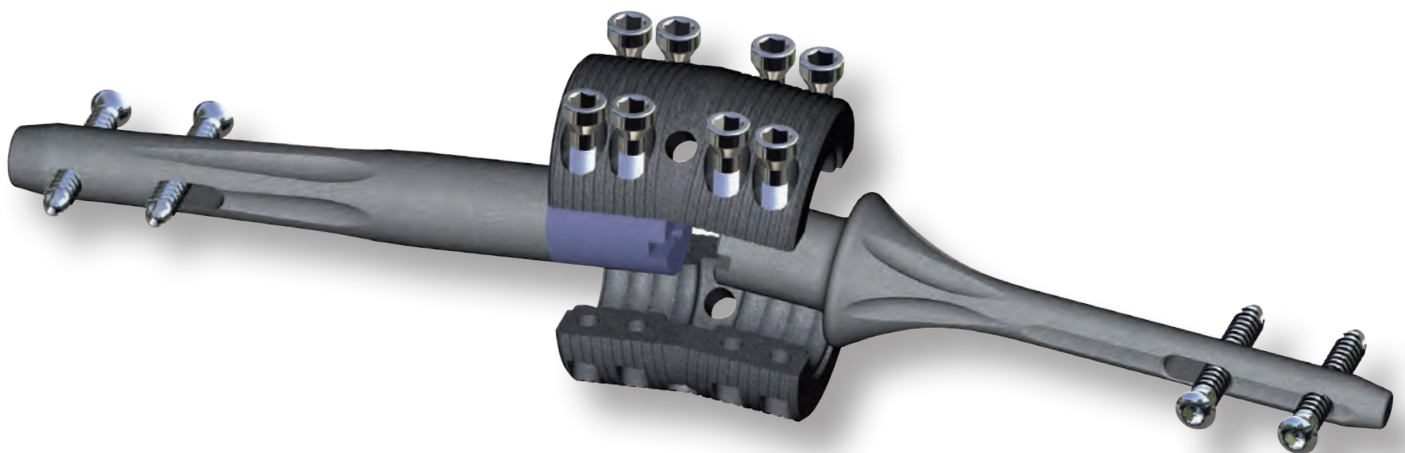


Indications

- Conditions resulting from previous operations such as joint reconstruction (osteotomy), arthrodesis or knee prosthesis,
- posttraumatic condition preventing an implantation of a knee prosthesis,
- loosening or impairment of the pulley,
- neuromuscular indications,
- infections, which require immediate weight bearing of the extremity and
- tumours in the region of the knee.

Contraindications

- Acute or chronic infections, local or systemic,
- severe muscle, nerve or vascular diseases, which would endanger the affected extremities,
- defective bone structures which would impede adequate anchoring of the implant,
- all accompanying diseases which could endanger the function and success of the implant and
- patients with mental or neurological disease conditions or patients who are not capable to follow the necessary postoperative treatment instructions.



System compatibility

For the implantation of the OsteoBridge™ Knee Arthrodesis, only the provided OsteoBridge™ Knee Arthrodesis Instrument set has to be used! All nails of the system are compatible with the enclosed spacers, an exception being. The spacers GA04020 and GA04030, which can only be combined with nails without collar. Curved nails may only be used in the femur.

▶ Implant materials

All components of the implant are made from titanium alloy TiAl6V4 ELI (ISO 5832-3). The implant may be inserted without cement or implanted with cement (PMMA) according to the specifications supplied by the manufacturer.

Surgical technique

► Pre-operative planning

The surgical technique presented here is used to demonstrate the fundamental procedure. Merete Medical, as the manufacturer of these devices, does not recommend this or any other treatment for use on a particular patient. The surgeon is responsible for determining and utilizing the appropriate treatment for each individual patient.

The pre-operative planning has substantial influence on the success of the surgery. It is requisite for the correct implant choice. We will gladly support you with this.

For the pre-operative planning there are two x-ray templates available (Ref. GARS001/GARS002). These show the angled spacer and one type of nail each in the lengths up to 150 mm in the offered diameters. With these the nail diameters and lengths can be determined pre-operatively. It can also be determined pre-operatively if the Standard System is sufficient to bridge the defect. Otherwise the lengths of the additional spacers can be determined based on the remaining gap. The choice of the implants can be performed intra-operatively with trial components.

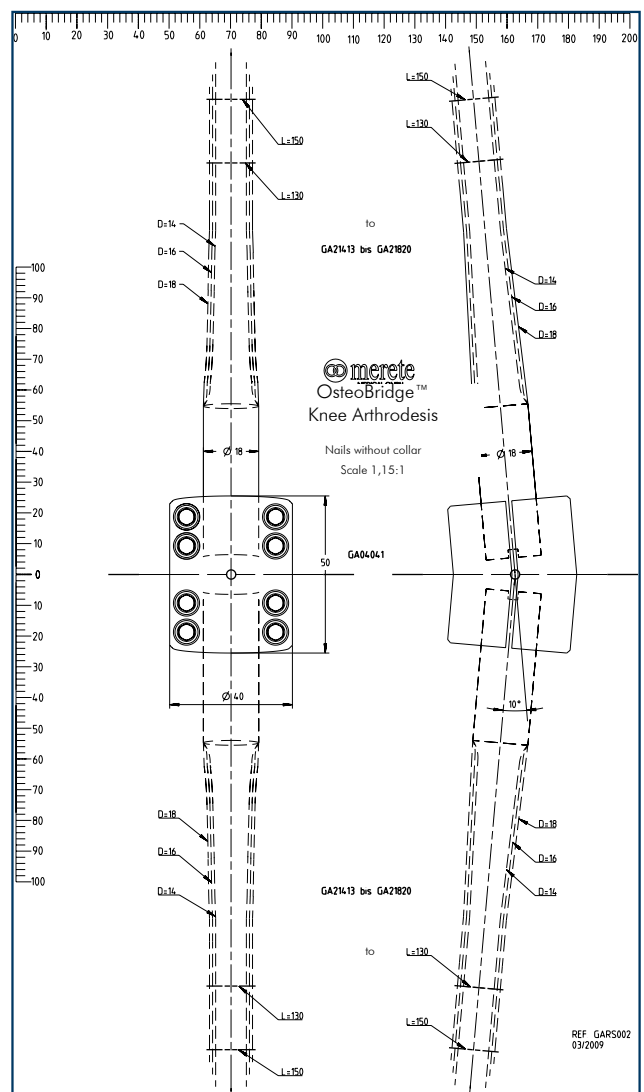
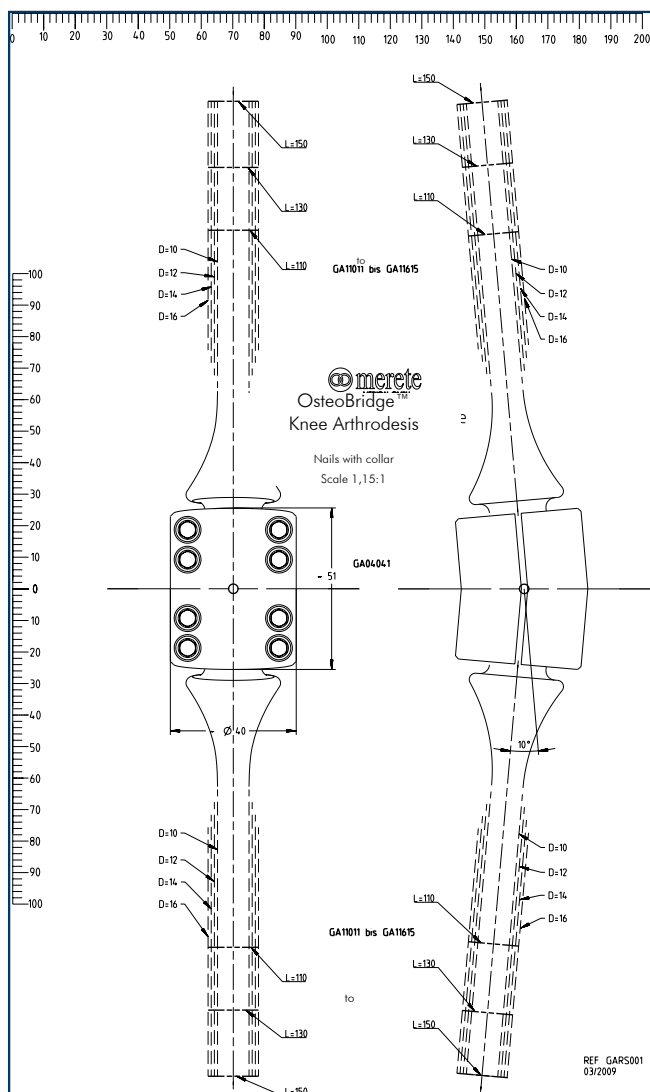
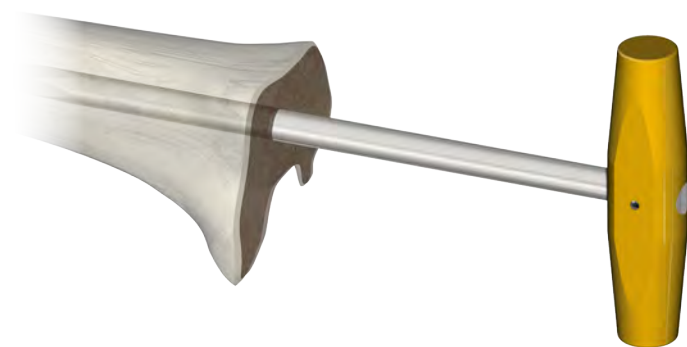


Figure 1 X-ray templates

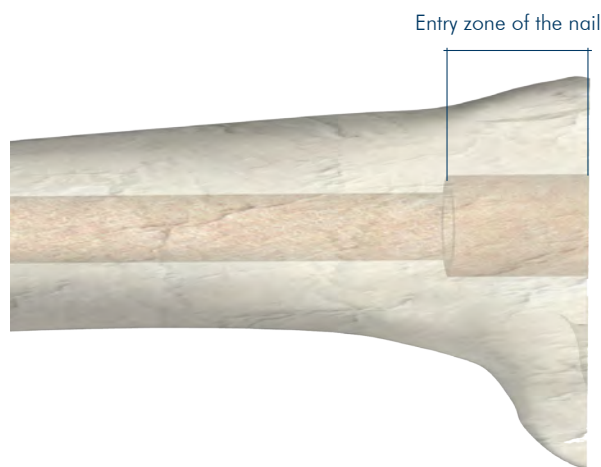
► Preparing the medullary canal

For the implantation of the OsteoBridge™ Knee Arthrodesis, only the provided OsteoBridge™ instrument set may be used. OsteoBridge™ is a disposable product and may not be reused. Parts with damage, damaged packaging or unknown intended use shall not be used.



Prepare the intramedullary canal by opening it with the bradawl (Ref. GA90020) or by drilling with an intramedullary drill (not included in the assortment) to the desired diameter. The drilled diameter varies depending on the nail form and the principle of anchoring (see chart 1 and 2).

Figure 2 Opening the intramedullary canal



When using nails without collar in a narrow medullar canal is, the medullar cavity should be opened additionally up to 20 mm (cemented) or 18 mm (cementless) in the entry zone of the nail (Figure 3).

Attention:

When the curved nails are being used, the drilled hole must follow the natural curve of the medullar canal.

Figure 3 Entry zone of the nail

Nail with collar



Nail Ø	Drill bit Ø cemented	Drill bit Ø cementless
Ø10 mm	14 mm	10 mm
Ø12 mm	16 mm	12 mm
Ø14 mm	18 mm	14 mm
Ø16 mm	20 mm	16 mm
Ø18 mm	22 mm	18 mm

chart 1

Nail without collar



Nail Ø	Drill bit Ø cemented	Drill bit Ø cementless
Ø14 mm	16 mm	12 mm
Ø16 mm	18 mm	14 mm
Ø18 mm	20 mm	16 mm
Ø20 mm	22 mm	18 mm

chart 2

In the condyle zone, the bone is usually opened in a trumpet like shape. The form of the nail with collar reflects this shape. With the aid of the reamer (Ref. GA90021), the bone can be shaped according to the nail. The line on the reamer marks the correct reaming depth.

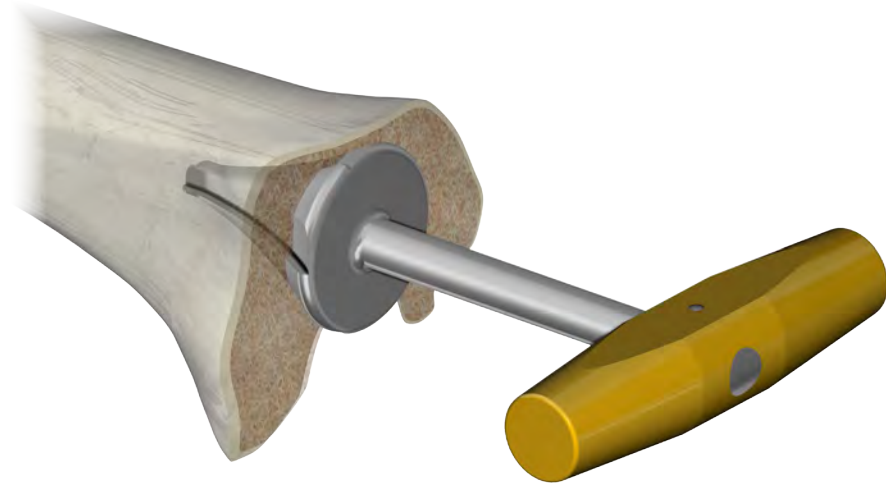


Figure 4 Application of reamer

► Implant choice

With the aid of the trial nails the adequate nail length and diameter can be controlled. Different nails can be used for tibia and femur.

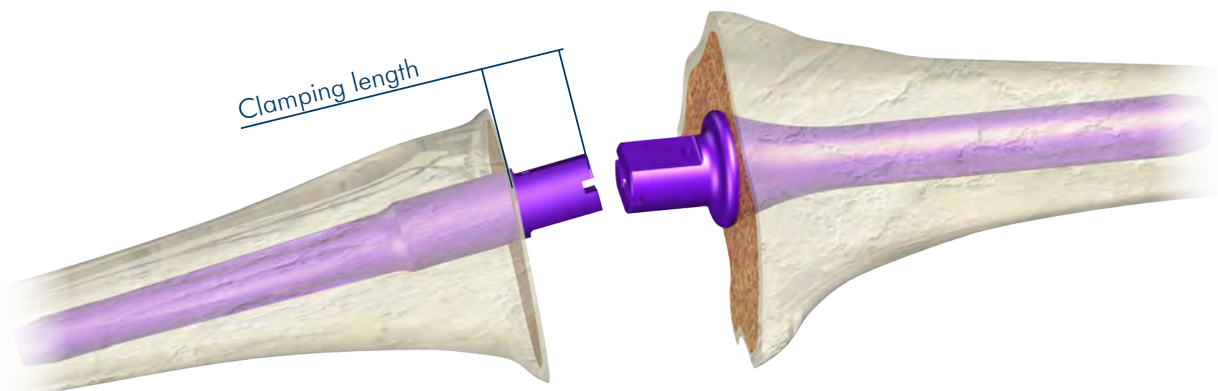


Figure 5 Trial nails

The nails have to remain at least 18 mm outside the bone. Should an additional spacer be placed onto a nail without collar, then the clamping length has to be fitted accordingly (max. 50 mm). The step within the trial nails shows the minimal clamping length.

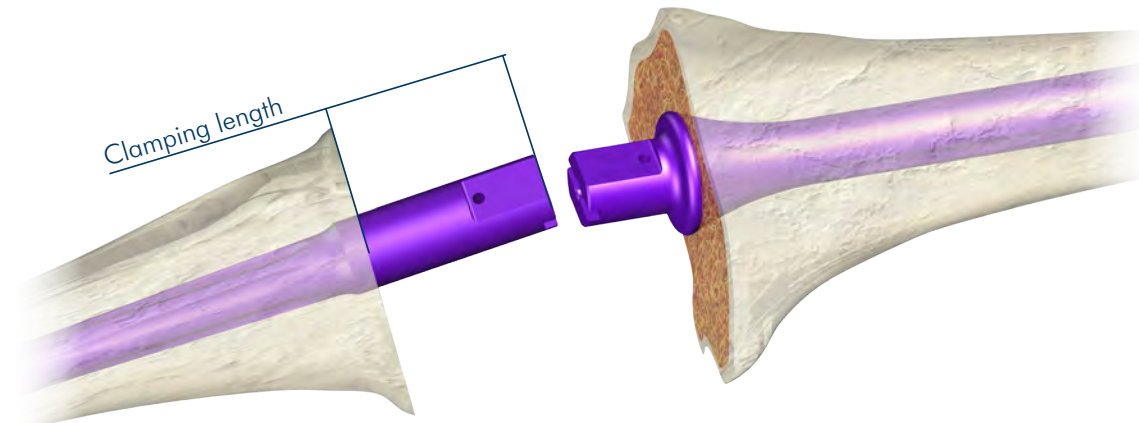


Figure 6 Maximum clamping length

For checking the total leg length the trial spacer (Ref. GA54041) has to be mounted. The upper spacer half shell is **guided by two pins and fastened by two screws**. If the leg length has the desired measure, the trial components have to be removed. In order to allow a good swinging compatibility of the leg, it should be slightly shortened.

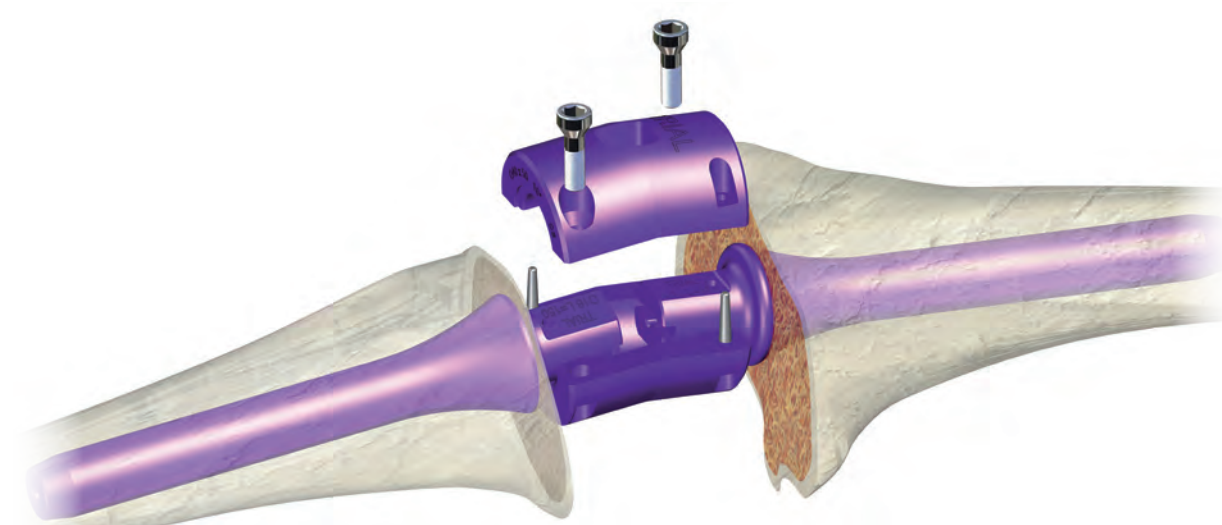


Figure 7 Mounting the trial spacer

For checking the position of the nails inside the spacer, there is a window on the upper part of the trial spacer. The nails have to be flush with the window.

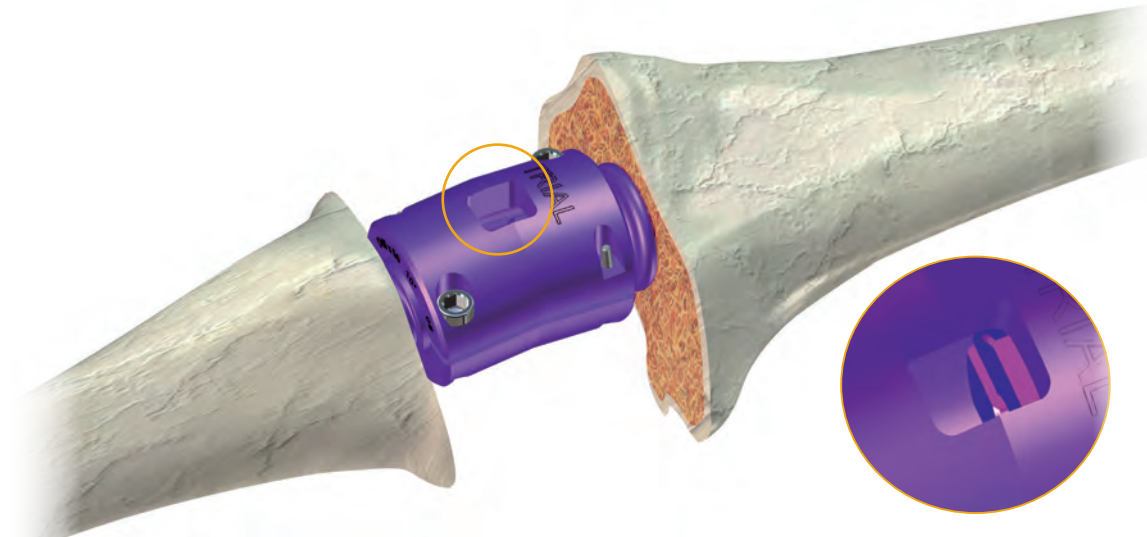


Figure 8 Positioning of the trial nails

If the angled spacer is not long enough to bridge the defect, the length of an additional spacer can be determined with the Spacer Gauge (Ref. GA90022). For this the Trial Spacer Connector (Ref. GA50040) is placed a one side of the spacer.



Figure 9 Application of the Spacer Gauge

To remove the trial nails or the implants, use the extractor (Ref. GB90203) and slotted hammer (Ref. AI00048). For this, screw the extractor into the proximal thread of the nail.

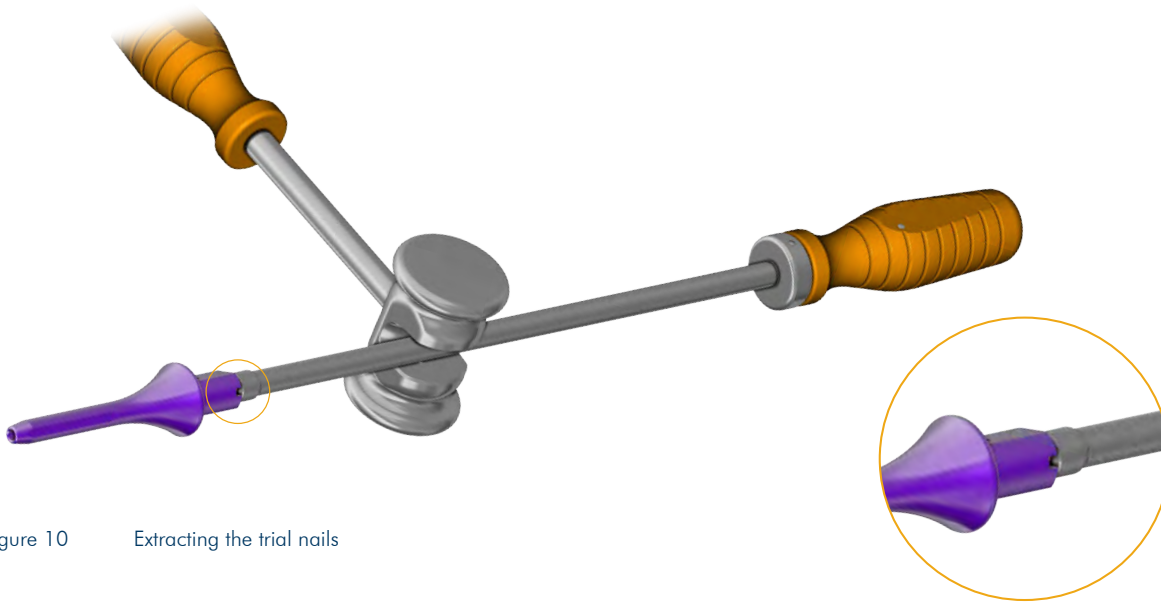


Figure 10 Extracting the trial nails

For a better allocation, the trial nails are labeled. Pictograms show the size of the nail diameter. The number of the dice can also be found on the product label.

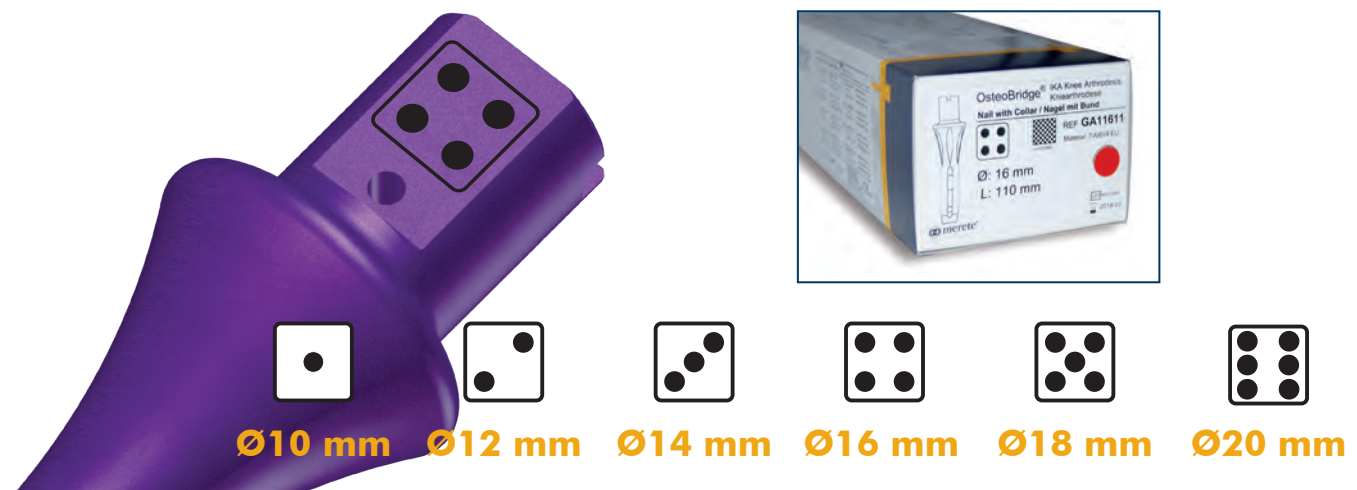


Figure 11 Labeling of nail diameter

Attention:

There are no trial nails available for the nails of the optional extension of the standard assortment (nails with collar Ø18 mm and nails without collar Ø20 mm).

► Insertion of the nails

The nails can be inserted cementless or cemented.

- Cementless

When using interlocking screws, the drill holes in the nail have to be positioned in the direction of the locking (i.e. lateral). For this, the guiding instrument (Ref. GA90100) has to be plugged into the slot of the proximal end of the nail and the setscrew has to be adjusted, until the nail has a tight fit on the guiding instrument. Now the nail can be brought into the right position inside the bone. The distance piece alongside of the nail indicates, how far the nail can be inserted into the bone.

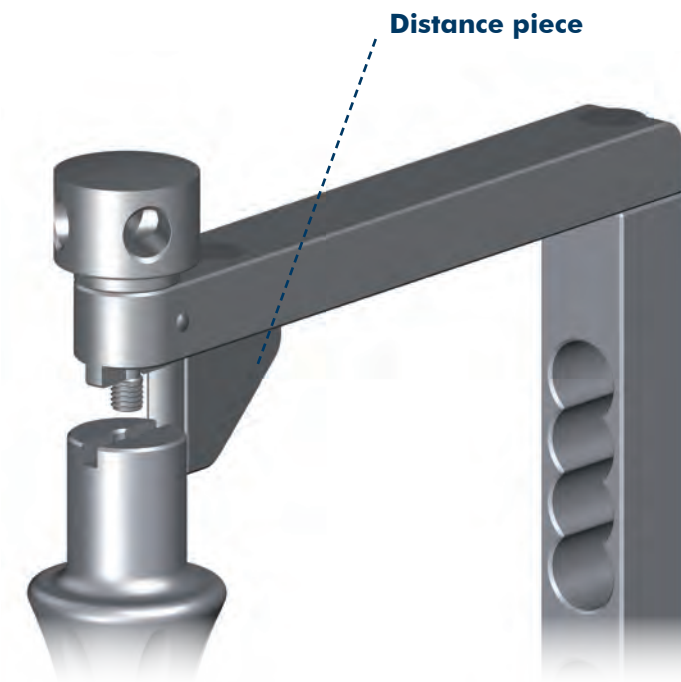


Figure 12 with locking

Optionally the impacting instrument (Ref. GA90008) can be used. The nail can be inserted into the bone as far as it will go.

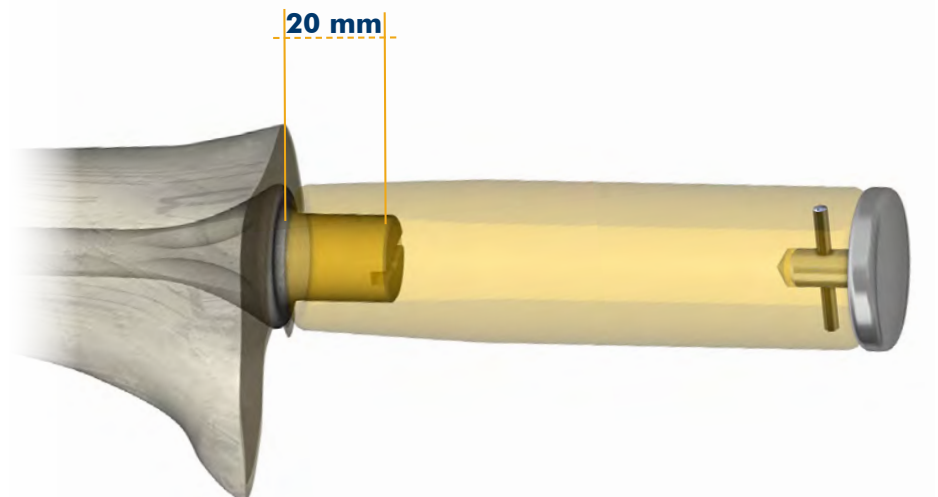


Figure 13 without locking

Interlocking the nails: The length of the nails whose drill holes align is indicated on the nail guiding/impacting instrument. The protection sleeve (Ref. GB90101) must be inserted into the corresponding hole of the guiding/impacting instrument, indicating the same length as the nail. The trocar peak (Ref. GB90102) center-punches the drill hole. The trocar is removed from the protection sleeve and the drill sleeve (Ref. GB90145) is inserted.

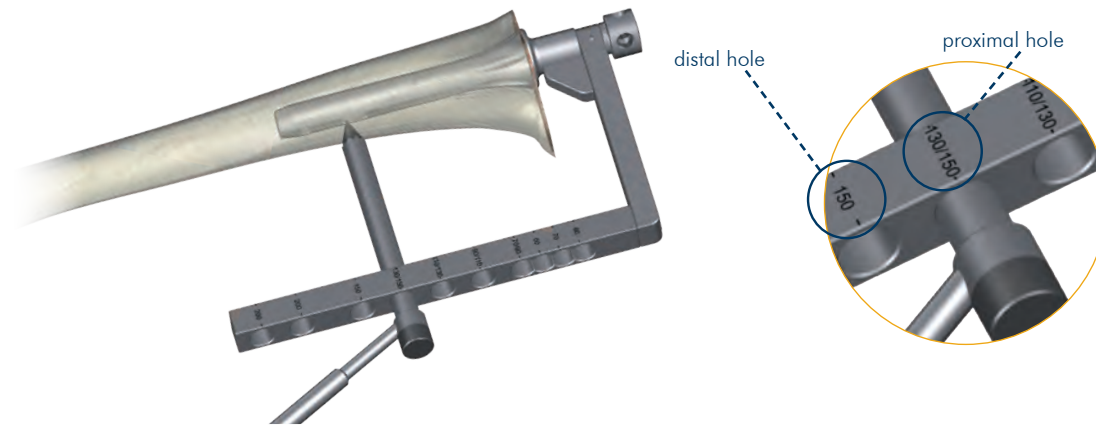


Figure 14 Distal and proximal holes at a 150 mm long nail

Use the Ø4.5 mm drill bit (Ref. GB90245) to drill the interlocking hole. Afterwards remove the drill sleeve. With the aid of the scale on the drill bit or the depth gauge (Ref. AI00200) the needed screw length can be determined. Always round up to the next larger even size.



Figure 16 Depth gauge

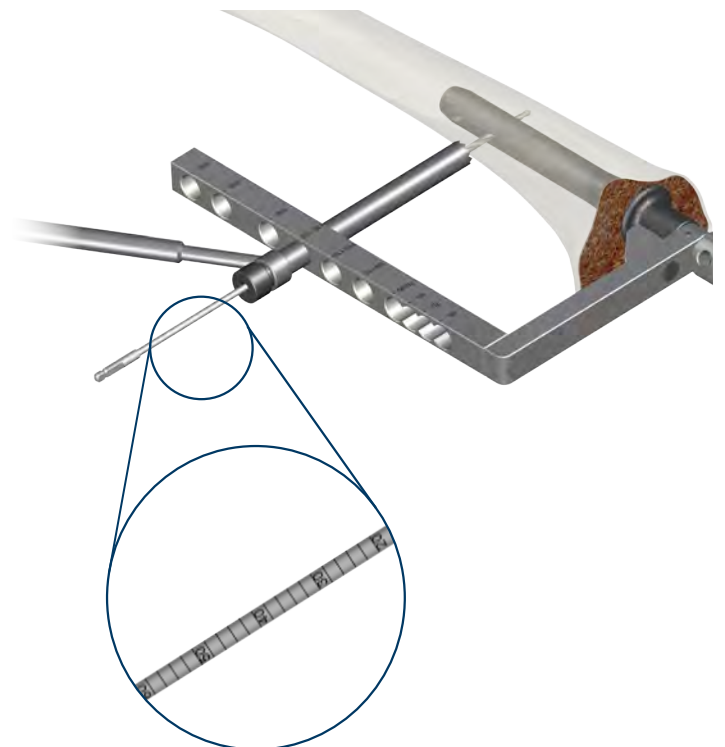
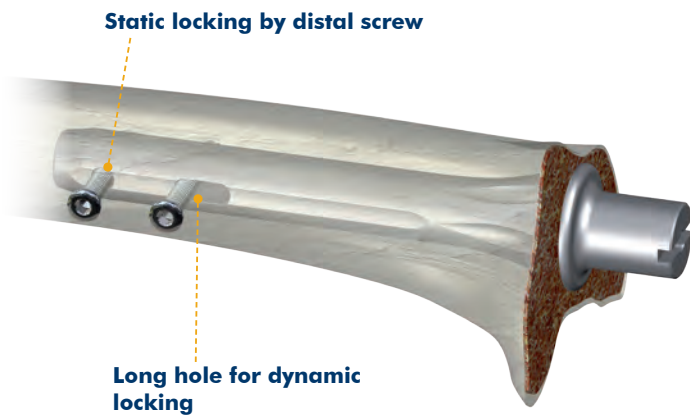


Figure 15 Labelled drill bit

The depth gauge (Ref. AI00200) is slid through the protection sleeve and positioned on the bone. The small measuring pole is pushed through the bone and hooked to the opposite cortical bone. Now the required length of the interlocking screw can be determine at the end of the measure.



Insert the interlocking screw of the correct length into the protection sleeve and tighten with the enclosed screwdriver (Ref. AI00135). All nails are provided with two holes for double interlocking. After the screws have been inserted, the nail guiding instrument can be removed. Only after the first nail has been completely locked inside the bone, the locking of the second nail can be performed.

By removing the static interlocking screw after several months, a dynamization of the nail can be achieved through the long hole.

Figure 17 Locked nail

- Cemented

For a cemented anchorage the cover sleeves have to be placed onto the nails before insert the nail. The sleeves are removed after the insertion of the nails has been completed. The intramedullary canal has to directly prepared according to chart 1 and 2 on page 9 to achieve a cement sheath of 2 mm. Nails can be inserted into the bone using either the cement protection caps (Ref. GA90002), or the guiding/impacting instrument together with the cement protection caps directly (Ref. GA90025).

Attention:

Additional interlocking when using bone cement is **strictly prohibited**.

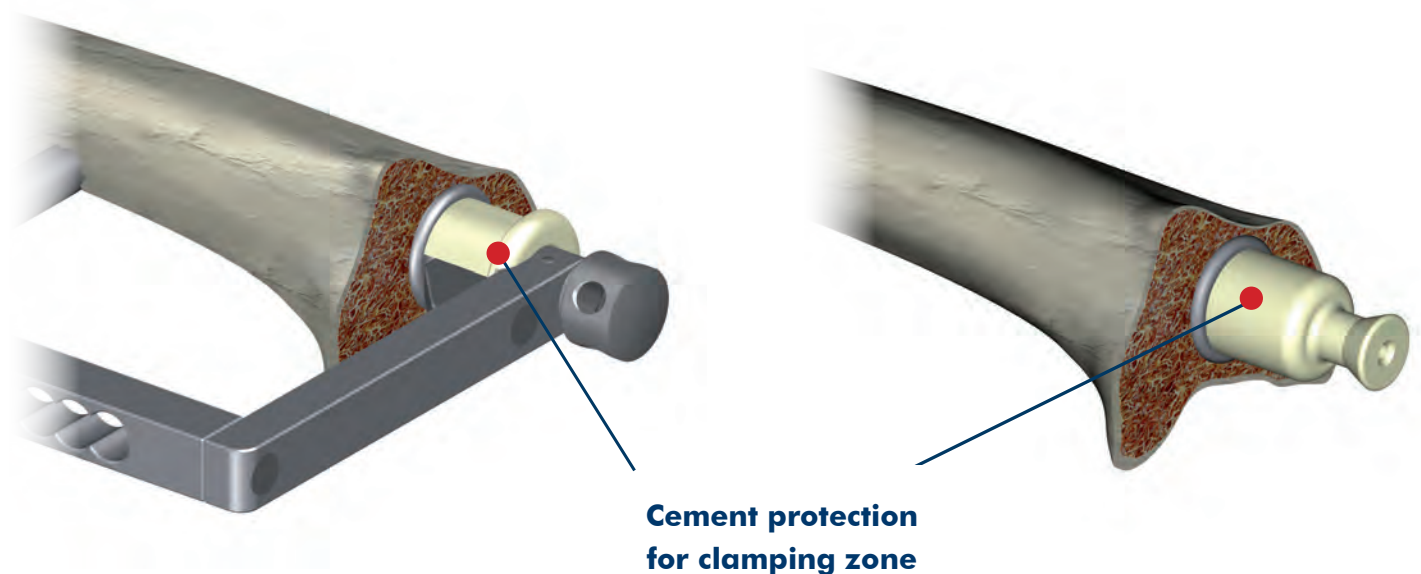


Figure 18 Cement protection of the nails

- Curved nails

Attention:

Curved nails must only be used in the femur.

Nails in the lengths 250 mm and 300 mm must be locked free hand using an image converter. They can be inserted using either the guiding/impacting instrument or the impactor.

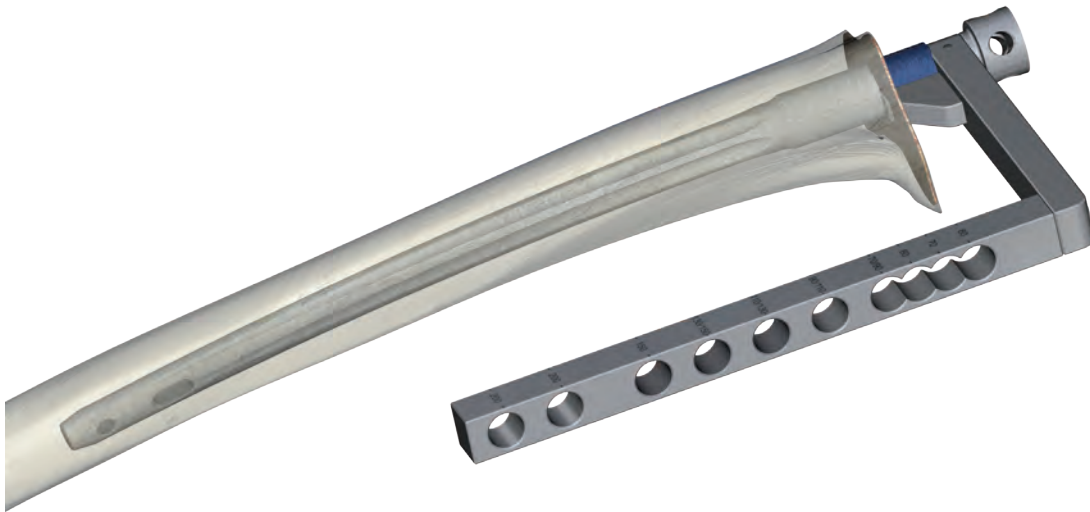


Figure 19 Insertion of the curved nails

► Insertion and assembling of the spacer

In order to implant the spacer, the lower half-shell is positioned underneath the nails. Always observe the minimal clamping length of 18 mm! It is not allowed to be less.

For this, the blue area must be entirely positioned inside the spacer. To ensure proper alignment of the half shells, four guide pins (Ref. GA90003) are included in the instrument set. To begin, screw the four guide pins into the outer threaded drill holes of the half shell. Resting the knee in a slightly angled position simplifies the correct mounting of the spacer.

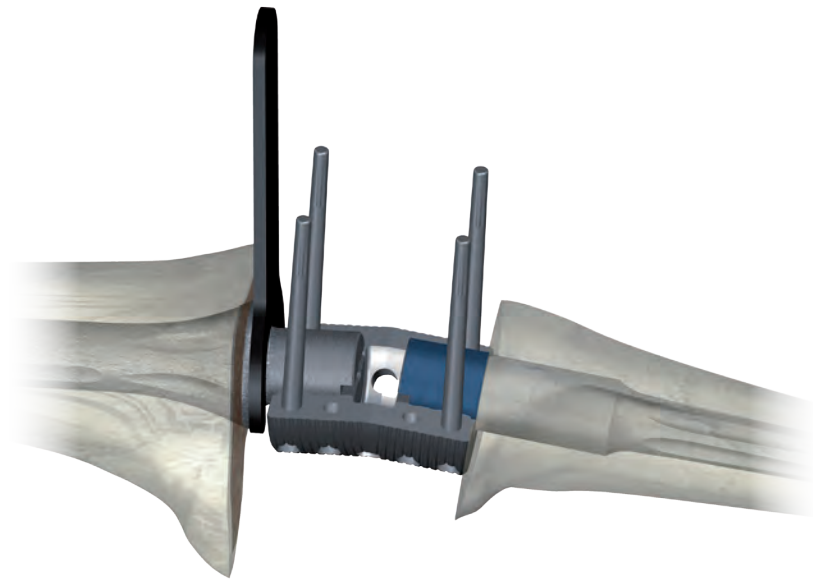


Figure 20 Assemblage Standard System

If an additional spacer must be clamped onto the nail, then the nail has to protrude out of the bone correspondingly (Figure 21).

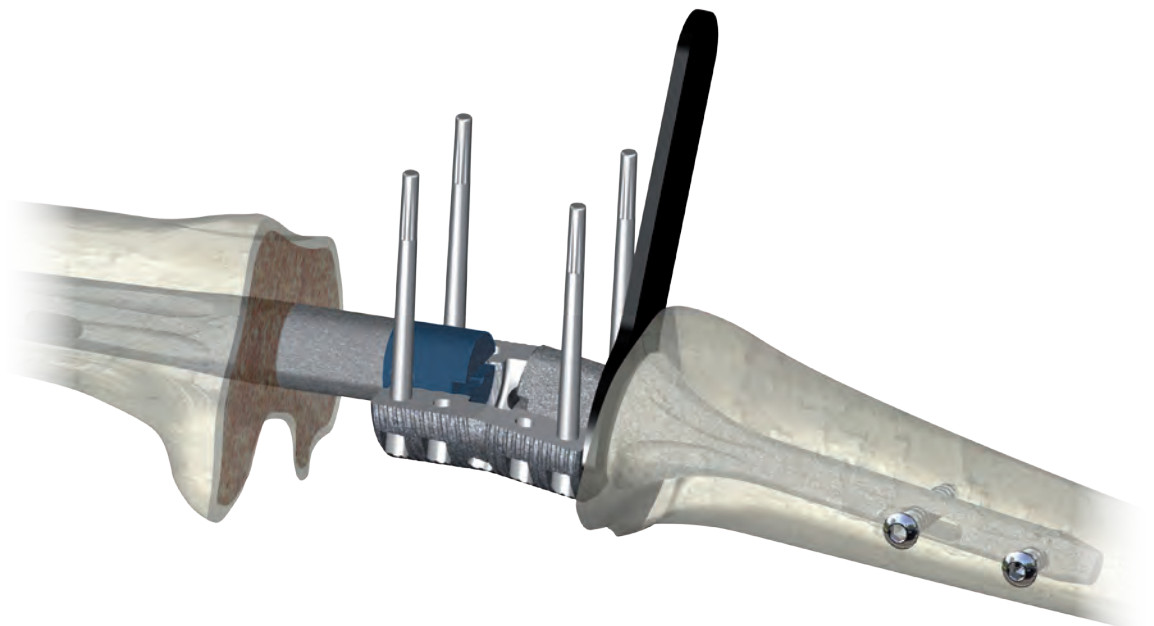


Figure 21 Assemblage Extended System

When using the **Extended System PLUS**, connector must be used on one side of the spacer a spacer instead of a nail. The spacer connector has to be pushed up against the side of the spacer.

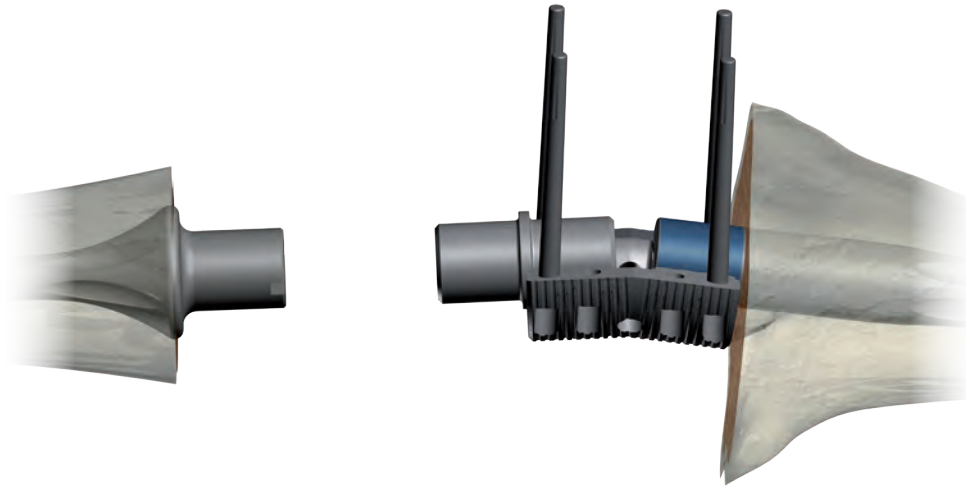


Figure 22 Assemblage Extended System PLUS

Between spacer and each nail with collar a distance holder (Ref. GA90007) is inserted. This determines the distance which is necessary for implantation. The dot on the distance holder should face away from the spacer. In the four free holes, clamping screws have to be screwed, but not tightened entirely. The adjustment of the rotation of the leg must now be done. To insert all spacer screws, the guide pins must be removed. Insert the remaining spacer screws. In addition to the 8 clamping screws each spacer has 2 spare spacer clamping screws.

Attention:

The two spacer half shells must be aligned parallel (equal distance on both sides) before evenly tightening the screws. An adjustment of the flexion or varus positioning of the joint can be achieved by rotation of the angled spacer.

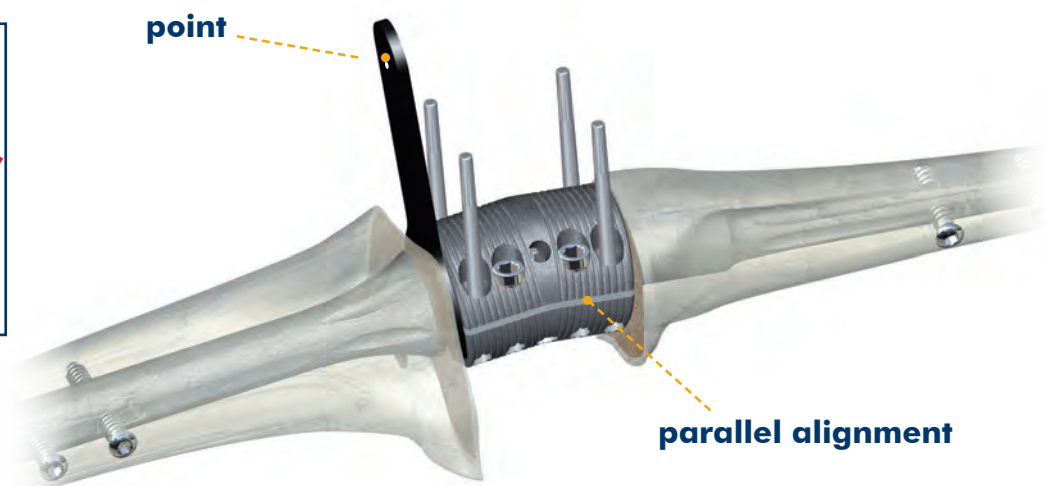
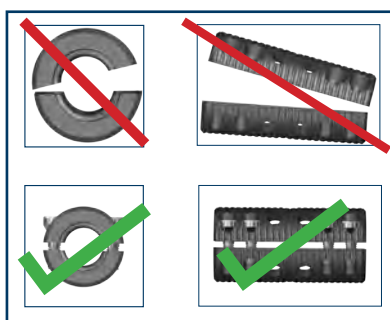


Figure 23 Alignment of the spacer

Important Information:

To avoid unbalanced clamping of the spacer, the final tightening of the clamping screws using the torque screwdriver must follow the pattern shown below:



Figure 24 Position the torque screw driver vertically on the screw

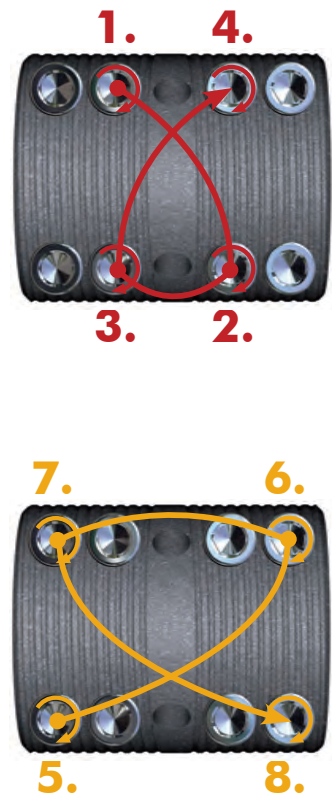


Figure 25 Tighten the screws in the described sequence

The torque screw driver consists of two pieces, the T-handle (Ref. GA90026) and the hex screw driver (Ref. GA90024) which are connected by a 1/4"-coupling.

Beginning with screw 1, the screws are tightened **crosswise** in strict rotation. Start with the inner four screws; afterwards tighten the outer four screws (see figure 25).

When torque is reached the torque limiting screw driver overwinds accompanied by a „click“.

All eight spacer screws must be tightened at least **three times** until torque indication, according to the described procedure, to equalize lengthening of the screws.

If a spacer of length 20 or 30 mm from the **Extended System** is used, it is placed on the clamping area of the nail without collar and bolted. The spacer must not clamp on the conical area of the nail. Leave a gap between the spacers to prevent abrasion. Tighten the clamping screws three times according to the instructions on figure 25.

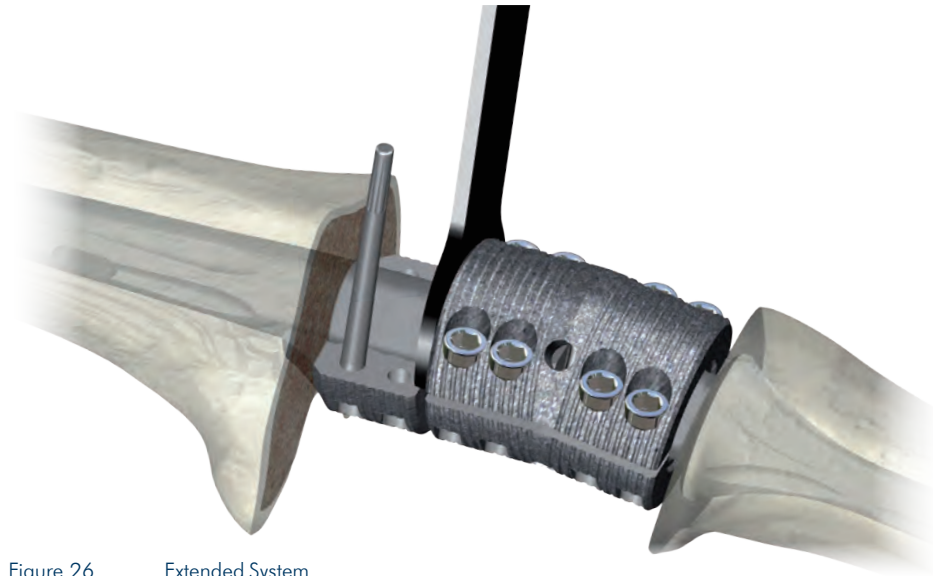


Figure 26 Extended System

When using a spacer with the length of 40 mm to 70 mm from the **Extended System PLUS** the spacer has to be assembled between the spacer connector and the nail only after the first spacer is fully mounted.

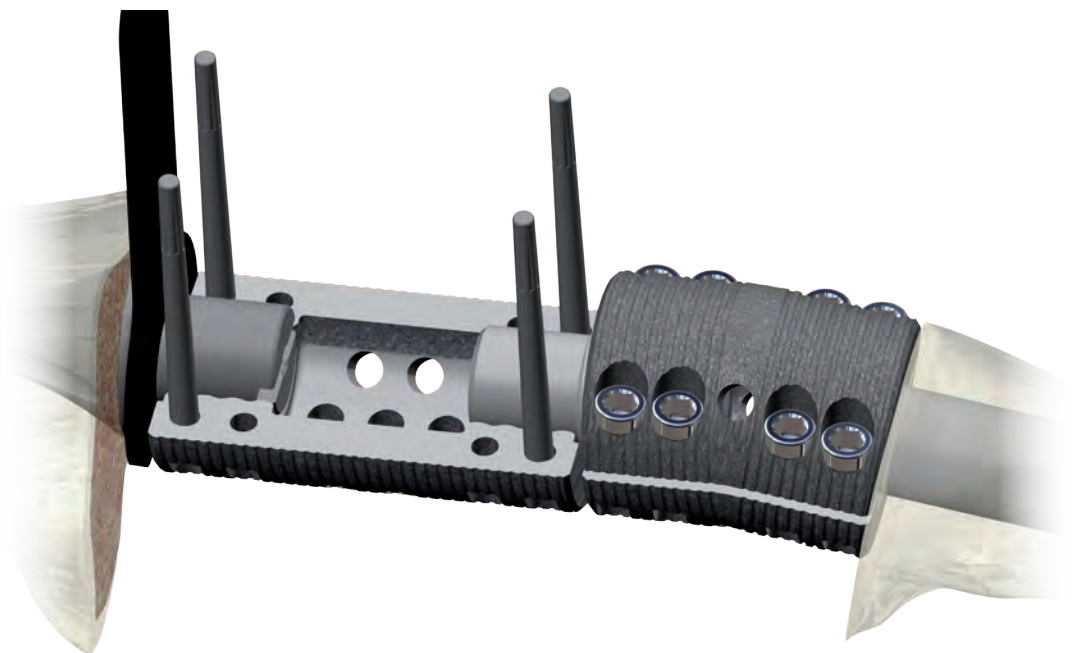


Figure 27 Extended System PLUS

Ordering information

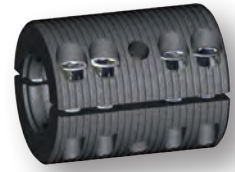
► Implants



Nail with collar*, sterile

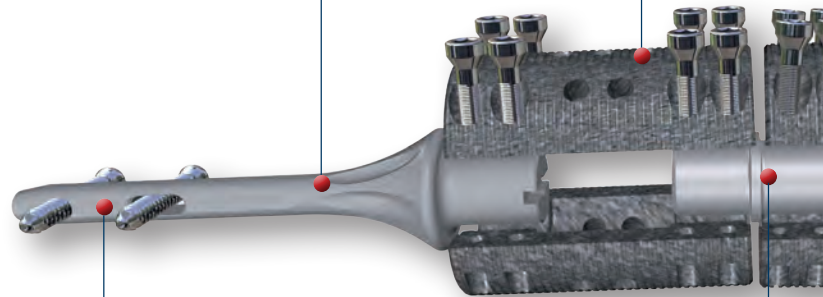
Length mm	Ømm	Ø=10	Ø=12	Ø=14	Ø=16	Ø=18**
	L = 130		GA11013	GA11213	GA11413	GA11613
L = 150		GA11015	GA11215	GA11415	GA11615	GA11815
L = 200		-	GA11220	GA11420	GA11620	GA11820

Spacer 70/60/50/40 mm, sterile



Diameter 40 mm, Angle 0°

Ref.	Length
GA04070	70 mm
GA04060	60 mm
GA04050	50 mm
GA04040	40 mm



Interlocking Screws, non sterile



Diameter 5 mm

Ref.	Length
GB35020	20 mm
GB35022	22 mm
GB35024	24 mm
GB35026	26 mm
GB35028	28 mm

Ref.	Length
GB35030	30 mm
GB35032	32 mm
GB35034	34 mm
GB35036	36 mm
GB35038	38 mm
GB35040	40 mm
GB35042	42 mm

Ref.	Length
GB35044	44 mm
GB35046	46 mm
GB35048	48 mm
GB35050	50 mm
GB35052	52 mm
GB35054	54 mm
GB35056	56 mm

60 mm and 65 mm Screws are available on request

*Patient specific nails are available on request

**Optional extension of the standard range (please place extra order)

**Spacer
angled, sterile**



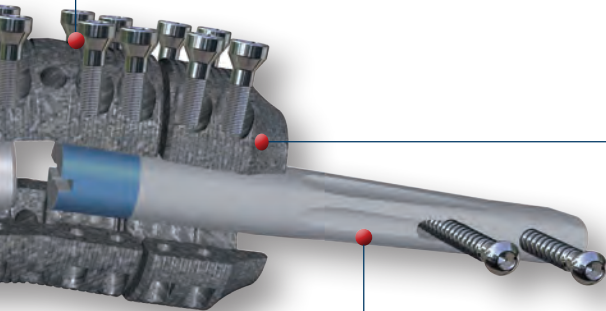
Diameter 40 mm, Angle 10°

Ref.	Length
GA04041	50 mm

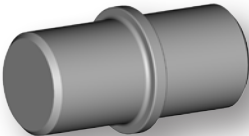
**Spacer
without / with collar, sterile**

Diameter 40 mm, Angle 0°

Ref. GA04020	Ref. GA04030
	
Length 20 mm	Length 30 mm



Spacer connector, sterile

Ref.	GA40040
	



Nail without collar*, sterile

	Ø in mm	Ø=14	Ø=16	Ø=18	Ø=20**
Length mm	L = 130	GA21413	GA21613	GA21813	-
	L = 150	GA21415	GA21615	GA21815	GA22015
	L = 200	GA21420	GA21620	GA21820	GA22020

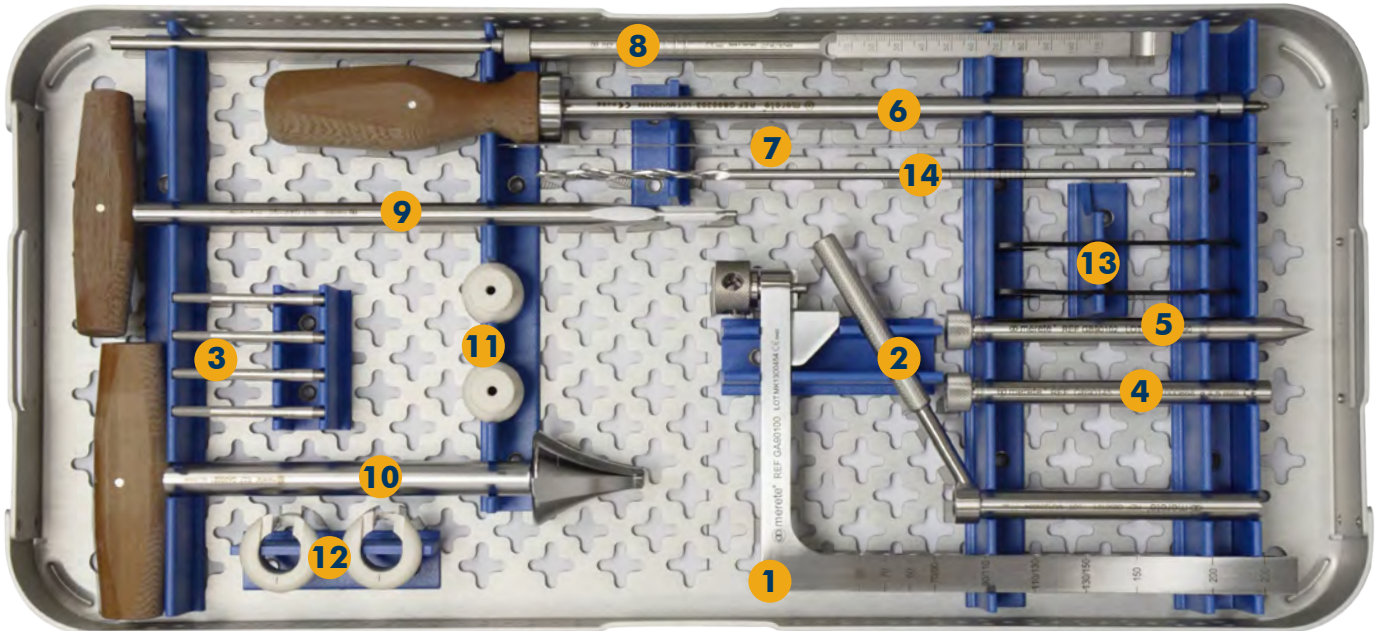


Nail without collar*, curved, sterile

	Ø in mm	Ø=14	Ø=16	Ø=18	Ø=20
Length mm	L = 250**	GA21425	GA21625	GA21825	GA22025
	L = 300**	GA21430	GA21630	GA21830	GA22030

► Instruments

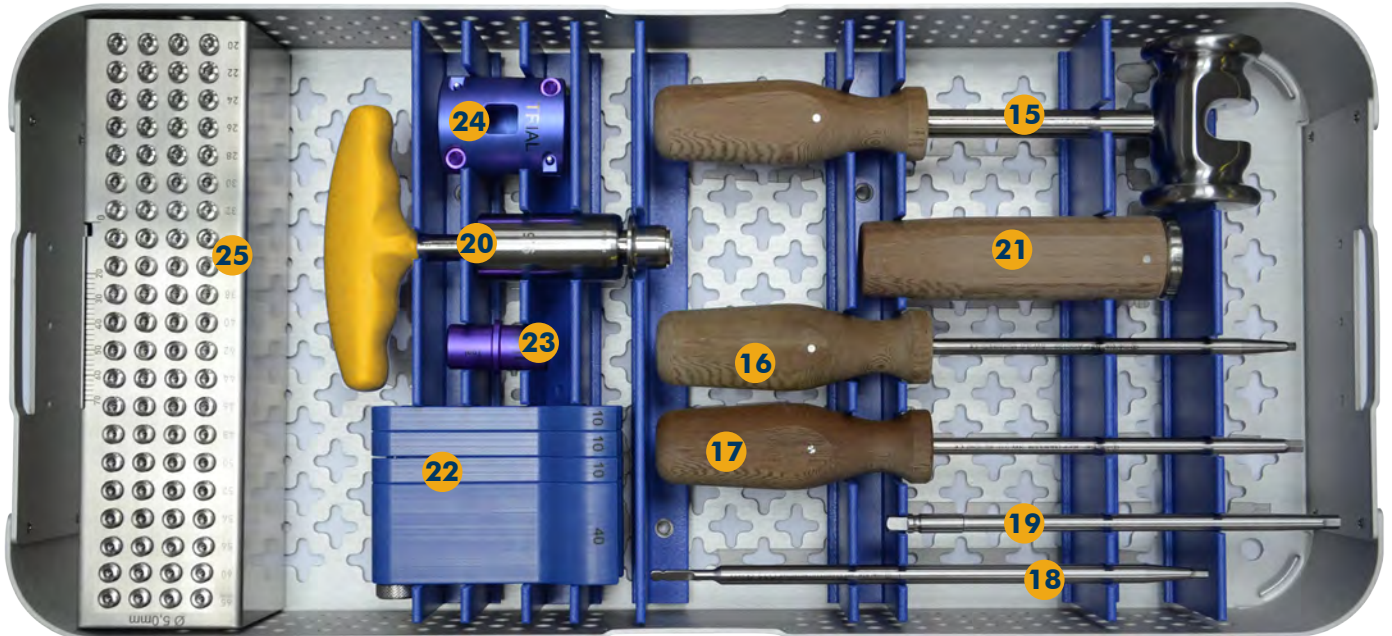
Instrument Tray 1	Ref. GA91001
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	Item	Ref.
1	Nail Guiding/ Impacting Instrument	GA90100
2	Protection Sleeve	GB90101
3	4x Guiding Pin	GA90003
4	Drill Sleeve for Ø4.5 mm drill	GB90145
5	Trocar	GB90102
6	Extractor	GB90203
7	300 mm Steel Ruler	AI90300
8	Depth Gauge	AI00200
9	Ø10 mm Manual Awl	GA90020
10	Reamer	GA90021
11	2x Cement Protection Cap (cement protection for nail)	GA90002
12	2x Protection Cap for use with Nail Guiding/Impacting Instrument	GA90025
13	2x Distance Holder	GA90007
14	Ø4.5 mm Drill with AO-connector for Ø5.0 mm Interlocking Screws	GB90245

Instrument Tray 2

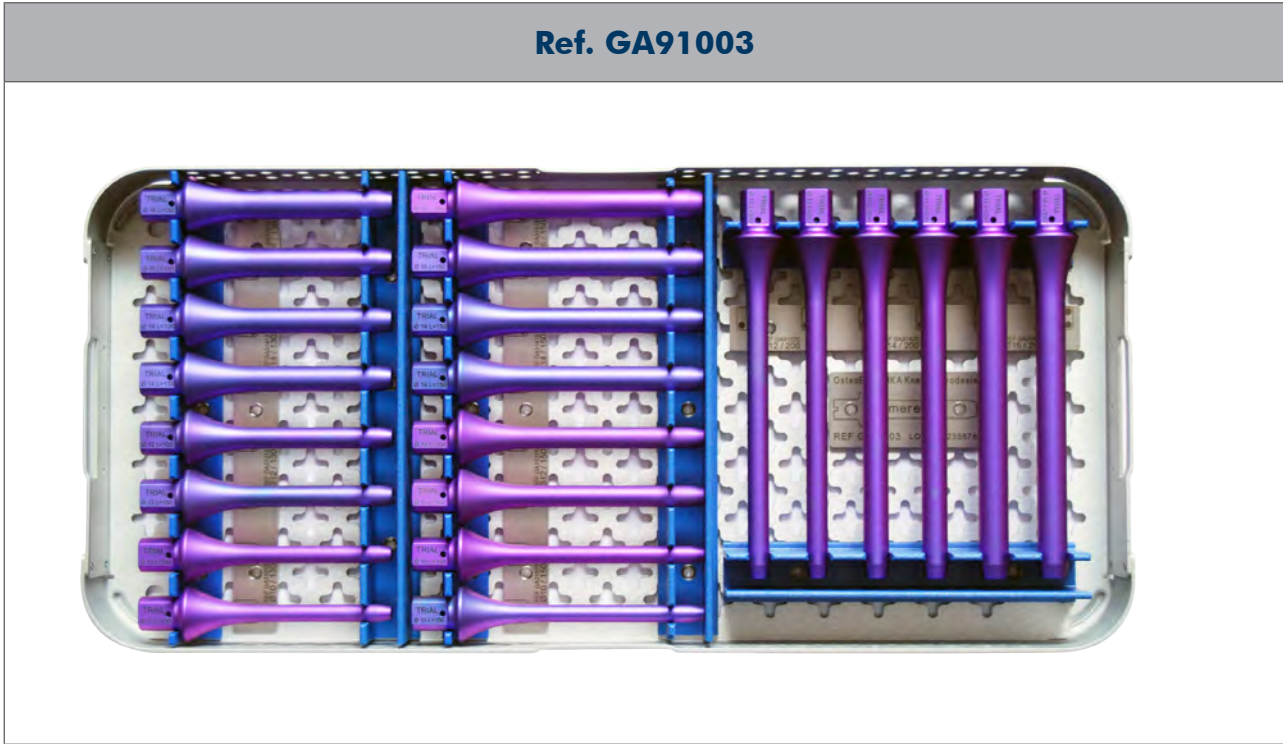
Ref. GA91002



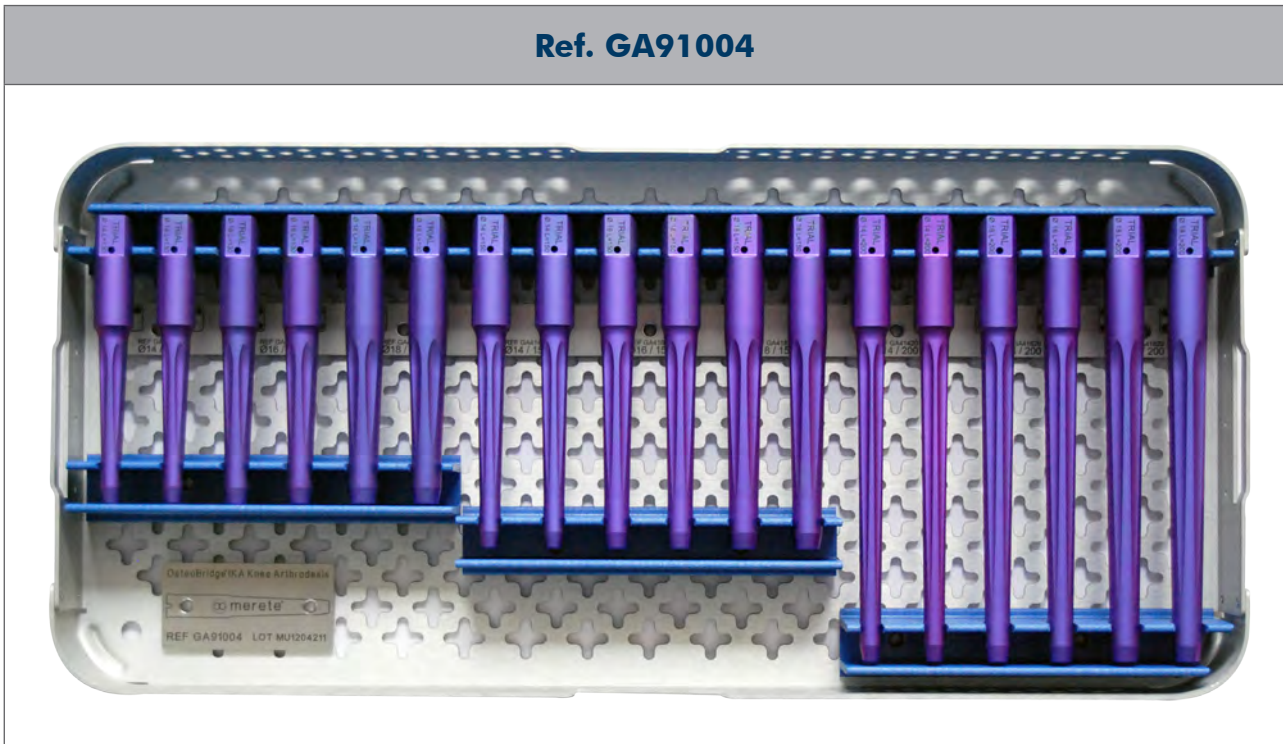
Item	Ref.
15 Slotted Hammer	AI00048
16 Hex 5.0 mm Screwdriver for Ø5.0 mm Clamping Screws	GA90009
17 Hex 3.5 mm Screwdriver for Ø5.0 mm Interlocking Screws	AI00135
18 Hex 3.5 mm Screwdriver with AO-connector for Ø5.0 mm Interlocking Screws	GA90023
19 Hex 5.0 mm Screwdriver with 1/4"-connector for Ø5.0 mm Clamping Screws	GA90024
20 Torque Limiter with T-handle and 1/4"-connector 9.5 Nm for Ø5.0 mm Clamping Screws	GA90026
21 Impactor	GA90008
22 Spacer Gauge	GA90022
23 Trial Spacer Connector	GA50040
24 Ø40 mm, 10°, l: 50 mm Trial Spacer	GA54041
25 4x Ø5.0 mm Interlocking Screws	GB35020- GB35056

▶ Trial Nails

Trial Nail Tray with 2 Trial Nails with collar each size

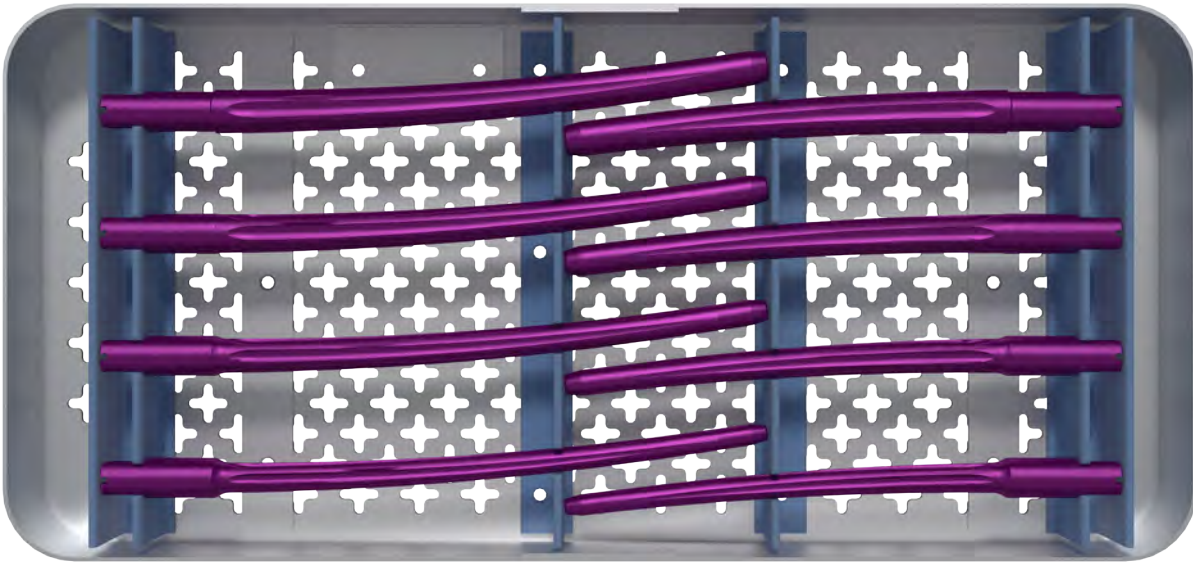


Trial Nail Tray with 2 Trial Nails without collar each size



Trial Nail Tray with 2 Trial Nails without collar each size, curved

Ref. GA91009



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