merete®

OsteoBridge™ IKA
Intramedullary Knee Arthrodesis

Surgical Technique and Ordering Information

This surgical technique applies only to the U.S.

OsteoBridge™
Merete® Limb Salvage Systems

merete®

Caution

Federal law restricts this device to sale by or on the order of a physician.

Caution

The following product descriptions contain detailed information on the recommended procedure (and associated surgical techniques) for Merete® implants and instruments. Training in the correct handling of implants and instruments is only to be executed by an authorized Merete representative.

Table of Contents

1. Description

Warning

Use of implants contrary to intended purpose. Risk of injury due to implant failure! Implant must only be used in accordance with intended purpose.

OsteoBridge™ Intramedullary Knee Arthrodesis Rod Fixation System (IKA) is a series of modular intramedullary rod segments that may be used as either proximal or distal segments. The segments are designed to be attached together to form a complete intramedullary rod using a semicircular hollow angled attachment shell that is clamped together with multiple screws to create a firm fixation of the bone. We strongly recommend covering the attachment shell with bone graft to enhance callus formation. All components are manufactured from Ti-6Al-4V ELI conforming to ASTM F136/ISO 5832-3. The intramedullary rods can be fixed with interlocking screws with or without bone cement.

The system includes two nails and a spacer. Users can choose between straight collared nails and conical non-collared nails. The spacer is available with 10° flexion angle. The angled spacer can be rotated if needed to set the valgus or varus position of the knee. All nails and the spacer can be combined freely. Collared, straight nails are predominantly used for an improved tibial fit, while non-collared, tapered nails are mostly used up to the mid-shaft position within the femoral canal. The non-collared, curved nails are commonly used to provide an extended interface throughout the canal.

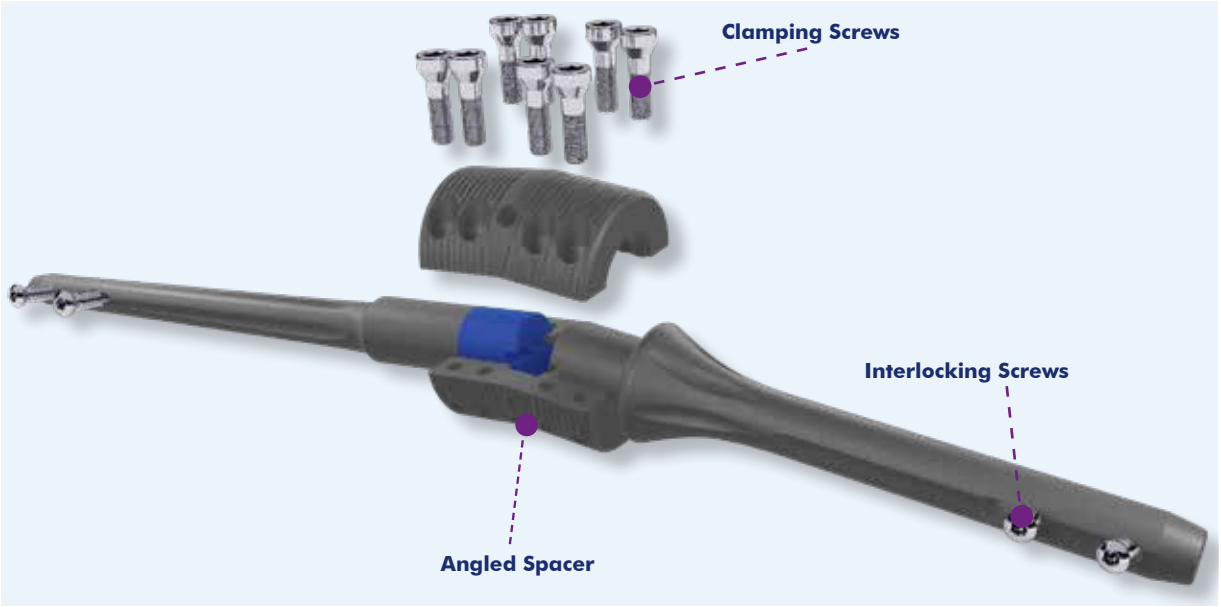


Figure 1: Complete Assembly: OsteoBridge™ Intramedullary Knee Arthodesis Nail Fixation System (IKA).

1.1. Indications

Intramedullary Knee Arthrodesis (IKA)

Indications include:

- Irretrievably failed total knee arthroplasty
- Limb salvage
- Oncology surgery
- Any other condition where there is little soft tissue or bony tissue available for support and arthrodesis is the treatment of choice

The intramedullary rods can be fixed with interlocking screws or with bone cement according to the specifications supplied by the cement manufacturer.

1.2. Contraindications

- Acute or chronic, local or systemic infections
- 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
- Patients with mental or neurological disease conditions or patients who are not capable of following the necessary postoperative treatment instructions

1.3. MRI Safety Information

 **MR Conditional**	**MRI Safety Information/Indications for Use** Non-clinical testing has demonstrated that the Merete OsteoBridge™ Intramedullary Knee Arthrodesis (IKA) system (consisting of two cemented or non-cemented intramedullary stems and one spacer made of TiAl6V4 ELI (ISO 5832-3)) is MR conditional. A patient with the entire assembled Merete OsteoBridge™ Intramedullary Knee Arthrodesis (IKA) system can be safely scanned in an MR system meeting the following conditions: • Static magnetic field of 1.5 Tesla and 3.0 Tesla. • Maximum spatial gradient field of 3,000 Gauss/cm (30 T/m). • Maximum MR system reported whole-body-averaged specific absorption rate (SAR) at 1.5 Tesla or 3 Tesla of 1 W/kg for 15 minutes of scanning. Under the scan conditions defined above, the Merete OsteoBridge™ Intramedullary Knee Arthrodesis (IKA) system is expected to produce a maximum temperature rise of less than 6° C after 15 minutes of continuous scanning. • In non-clinical testing, the image artifact caused by the Merete OsteoBridge™ Intramedullary Knee Arthrodesis (IKA) system extends at least 1 cm and up to approximately 7 cm from the device and exhibits substantial geometric distortion in the image when imaged with a gradient echo pulse sequence or a fast-spin echo pulse sequence and a 1.5 Tesla MRI system or a 3.0 Tesla MRI system.

2. General Information

Warnings

Use of damaged or defective implants. Risk of injury due to premature implant failure! Implants with identifiable damage may not be used. Avoid notches, scratches or bending of the implant in order to preserve its stability.

Use of damaged or defective instruments. Risk of injury due to premature implant failure! Instruments with identifiable damage may not be used.

Improper use of an implant/instrument. Damage to/destruction of instrument/implant and injury to patient! Ensure correct handling of implant/instrument. Do not misuse.

Incorrect or improper assembly of implant. Risk of increased wear to implant! Risk of implant failure! Perform the implantation with care. Observe correct handling of implant components and instruments. A bicortical anchoring is essential for a stable implant when using interlocking screws. The interlocking screws must be completely tightened. Make sure there is at least 5 cm of cortical bone contact, in order to ensure stable anchorage of the nail within the bone. Prior to assembling the spacer, wash the clamping surface in order to completely remove all kinds of debris, including bone splinters, soft tissue parts, bone cement and others. It is essential to ensure that the implant nails are clamped in the spacer at their minimum respective clamp lengths and the spacer is flush with the clamping areas of the nails. The instructions for the assembling of the spacer with the spacer screws are to be followed exactly. All eight screws must be used for spacer assembly. Use the guiding pins during assembly to ensure the spacer half-shells remain parallel to each other. When screwing in the guiding pins or spacer screws, be careful not to damage the spacer threads. Use the distance holder during assembly to maintain the necessary gap between nail collar and spacer. Do not allow nails to contact each other inside spacer. In case of defective bone structure, the nail must be long enough to bridge over the damaged region.

Improper use of bone cement. Risk of injury due to premature implant failure!Pay attention to the information given by the cement manufacturer. The cement mantle should be spread evenly and be no thicker than 1-2 mm on each side. Cement protection caps must be placed on the nails before cementing to avoid contamination to the clamping surfaces.Combination with products from other manufacturers. Risk of injury due to implant failure! Do not combine the implant components with products from other manufacturers.

Use of implants which have been previously used. Risk of injury due to premature implant failure! Risk of sepsis! Implants are only approved for single use, not for reuse.

Implantation of trial implants. Risk of injury due to failure of trial implant! Only use trial implants in order to select a suitable permanent implant. Trial implants are not suitable for permanent implantation.

Use of contaminated implants/instruments. Risk of Sepsis! Use only implants/instruments without visible contamination.

Risk of infection due to non-sterile implants! Do not use implants whose packaging is damaged. Do not use implants whose expiry date has passed.

Foreign bodies (e.g. cement residues, tissue, bones) between implant components. Risk of injury due to implant failure! Thoroughly clean any foreign bodies from implant components.

Use of instruments with electrical energy. Risk of injury due to implant failure! Do not damage the surfaces of the implants under any circumstances.

Resterilization of implants. Risk of injury due to premature implant failure caused by adverse material changes! Implants delivered sterile by Merete GmbH must not be resterilized and/or repacked. Products for which expiry date has passed may be returned to Merete Technologies Inc. (MTI).

NOTE
Observe symbol on packaging: "Do not reuse".

3. System Compatibility

All system nails are compatible with the included spacer. Curved nails are only intended for use in the femur. When performing implantations, use only the Merete GmbH instruments expressly designed for that purpose.

Implant Materials

All implant components are made of titanium alloy TiAl6V4 ELI (ISO 5832-3). Implants may be inserted using non-cemented or cemented (PMMA) fixation according to manufacturer specifications.

4. Surgical Technique

4. Surgical Technique

4.1. Preoperative Planning

The surgical technique presented here serves only as an example to illustrate the basic procedure during implantation. Merete GmbH, manufacturer of this medical device, does not stipulate that this or any other treatment method is to be used for any specific patient. Selecting appropriate operational techniques for a particular patient is the responsibility of the operating physician. Merete GmbH bears no responsibility with regard to surgical technique selected for any individual patient.

Surgery planning should be done on the basis of in-depth evaluations of patient X-rays which provide the information necessary for determining the appropriate implant type, size and possible combinations. If desired, X-ray Templates (Figure 3) (Ref. GARS004) for preoperative planning are available from Merete. It should be examined preoperatively whether the existing implant sizes are suitable for the patient. It is also important to carry out preoperative tests on the patient to rule out allergic reaction to the implant materials. The components planned for implantation must be on hand in all available sizes.

When selecting nails, remember to subtract the 18 mm clamping length from the selected nail length (Figure 2). This shortens the nail's implantation length (see Table 1). Make sure there is at least 5 cm of cortical bone contact, in order to ensure stable anchorage of the nail within the bone. In case of defective bone structure, the nail must be long enough to bridge over the damaged region. The non-collared nails have a conical shape. After the extended clamping length of 50 mm, the nail is tapered from the nominal diameter (D1) by 4 mm (D2) (Figure 2).

Caution
Curved nails must only be used in the femur. Also, curved nails extend past the length of the Nail Guiding/Impacting Instrument (Ref. GA90100), their corresponding interlocking screws must be inserted under fluoroscopy without a guide.

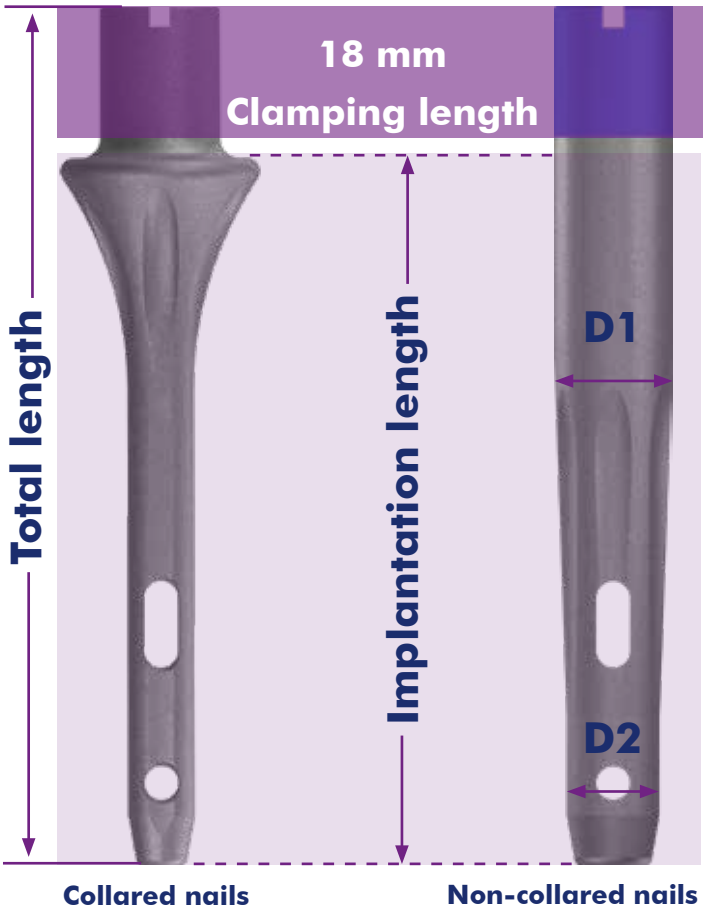


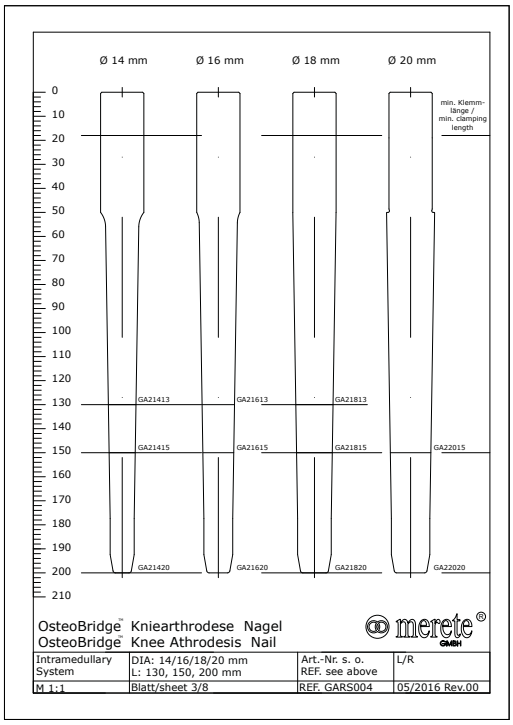
Figure 2: Nail length

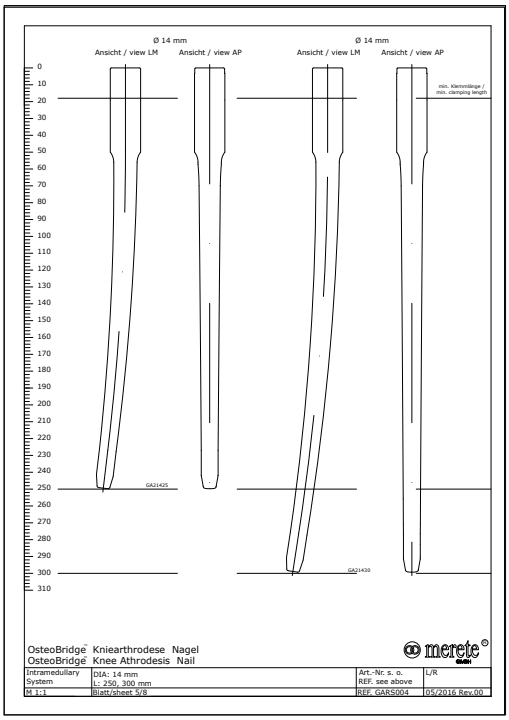
Table 1: Nail Total Length and Implantantion Length.

Collared nails/non-collared nails Size in mm	
Total length	**Implantation length**
130	112
150	132
200	182

Curved non-collared nails Size in mm	
Total length	**Implantation length**
250	232
300	282

Non-collared nails Size in mm	
Nominal Diameter (D1)	**Taper 4 mm (D2)**
DIA. 14	DIA. 10
DIA. 16	DIA. 12
DIA. 18	DIA. 14
DIA. 20	DIA. 16





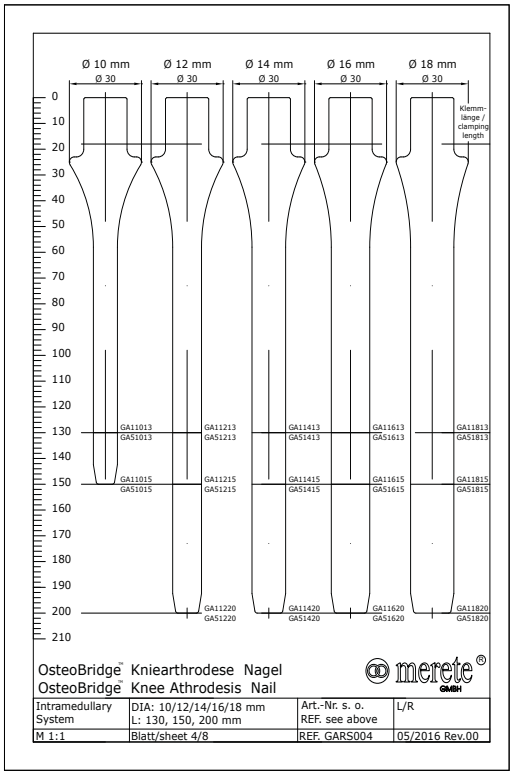


Figure 3: X-ray Templates

4.2. Preparing the Medullary Cavity

Warning

Incorrect preparation of the medullary cavity. Risk of implant failure (lengthening/shortening of the extremity)! Drill out the medullary cavity as specified in the surgical technique and use a cement restrictor when using bone cement to ensure a proper cement mantle.

Prepare the medullary cavity by opening it with the Manual Awl (Ref. GA90020) and use reamers **(not included)** to expand it to the desired diameter (Figure 4). The diameter will vary depending on the nail design and anchoring method being used (see Tables 2 and 3, Page 14). Make sure there is at least 5 cm of cortical bone contact, in order to ensure stable anchorage of the nail within the bone. In case of defective bone structure, the nail must be long enough to bridge over the damaged region.

Figure 4: 6.0 mm Manual Awl. Open medullary cavity with the Manual Awl.

In procedures involving non-collared nails and narrow medullary cavities, ream the medullary cavity out to 20 mm (cemented)/18 mm (non-cemented) in the nail entrance area (Figure 5).

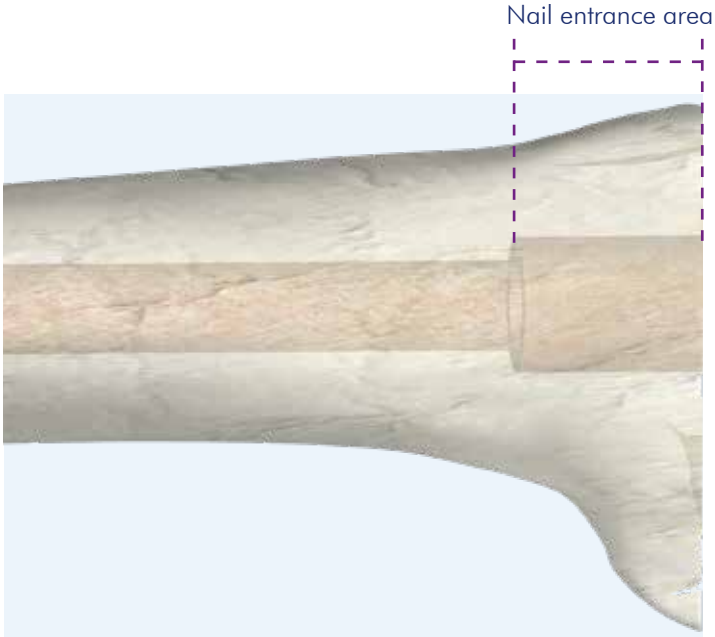


Figure 5: Nail entrance area.

NOTE

When using curved nails, the reaming channel must follow the natural curvature of the medullary cavity.

Collared Nail

Table 2: Collared Nails. Reaming for cemented and non-cemented implantation.

Nail DIA. Size in mm	**Drill DIA. for cemented implantation** Size in mm	**Drill DIA. for non-cemented implantation** Size in mm
10	14	10
12	16	12
14	18	14
16	20	16
18	22	18

Non-collared Nail / Non-collared Curved Nail

Table 3: Non-Collared/Curved Nails. Reaming for cemented and non-cemented implantation.

Nail DIA. Size in mm	**Drill DIA. for cemented implantation** Size in mm	**Drill DIA. for non-cemented implantation** Size in mm
14	16	12
16	18	14
18	20	16
20	22	18

NOTE

Because of their funnel-shaped design, nails with a collar may cause a splitting or shattering effect (fissure) in the distal femur (condylar region) and the proximal tibia (plateau region) during implantation. Careful preparation of these bone regions, with the correct instrument and if applicable a proper cement mantle, are required.

The bone usually opens out into a trumpet shape in the femoral condyle and tibial plateau area. The shape of the collared nails reflects this form. The Reamer (Ref. GA90021) can be used to adapt the bone to the design of the nail in the proximal area. The line on the reamer marks the correct depth of reaming (Figure 6).

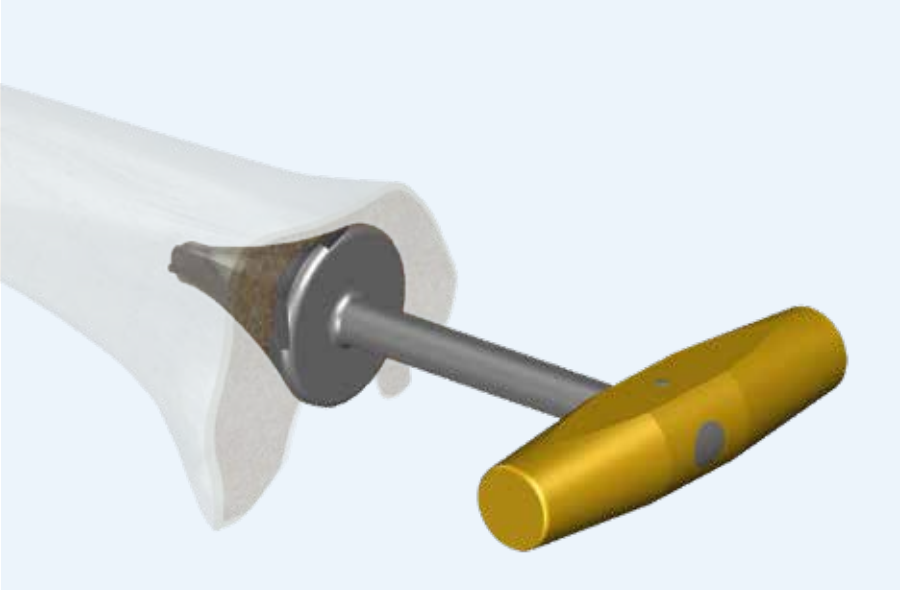


Figure 6: Using the Reamer (Ref. GA90021).

4.3. Implant Selection

Warning

Implantation of trial implants. Risk of injury due to failure of trial implant! Only use trial implants in order to select a suitable permanent implant. Trial implants are not suitable for permanent implantation.

Trial nails can be used to check appropriate nail diameters and lengths. Different nails can be used in the tibia and the femur (Figure 7).

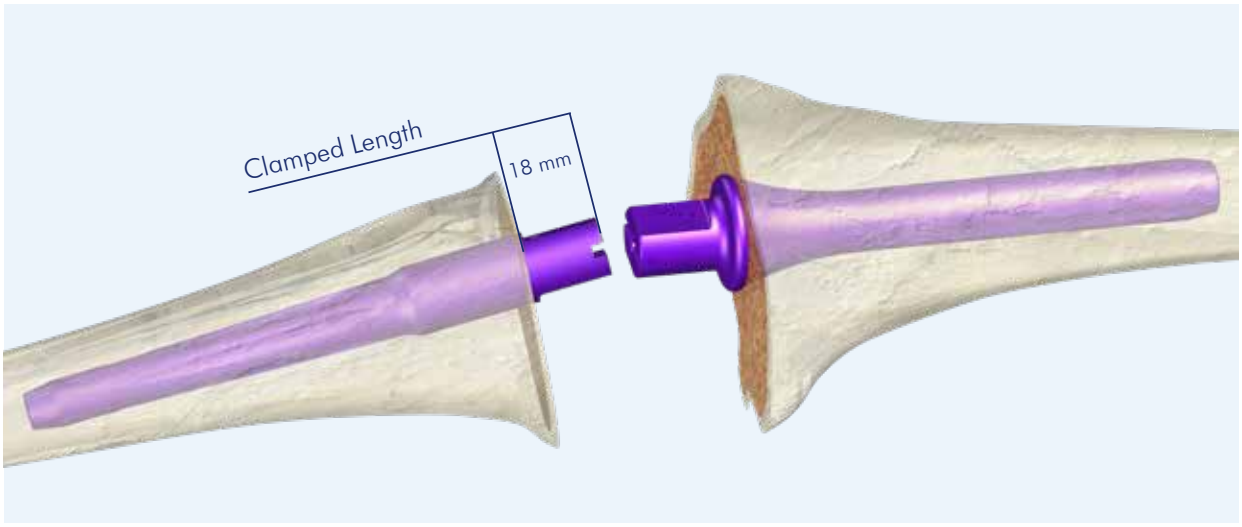


Figure 7: Trial Nails.

The nails must protrude out from the bone by at least 18 mm. The section marking on the trial nails shows the minimum clamped length for the spacer.

Use the lower Trial Spacer half-shell (Ref. GA54041) to check the total length of the leg. Guide the upper Trial Spacer half-shell **over the two pins of the lower half spacer and anchor it with the two screws** (Figure 8). Postoperatively, the leg should be shortened slightly to ensure that it will be able to swing freely.

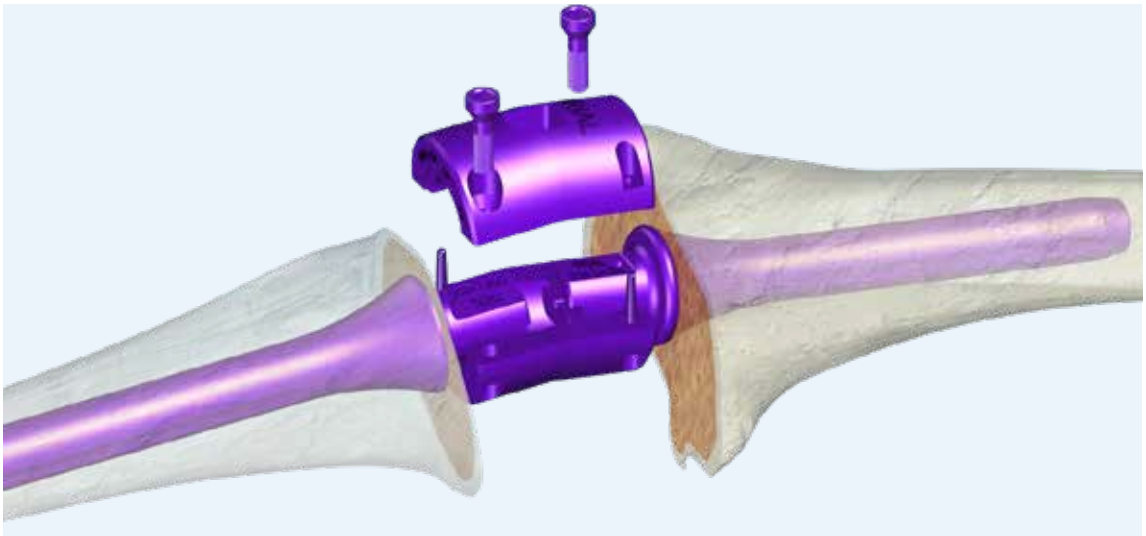


Figure 8: Mounting the Trial Spacer.

The window on the top of the trial spacer shall be used to check the position of the nails in the spacer. The nails must at least be flush with edge of the window (Figure 9).

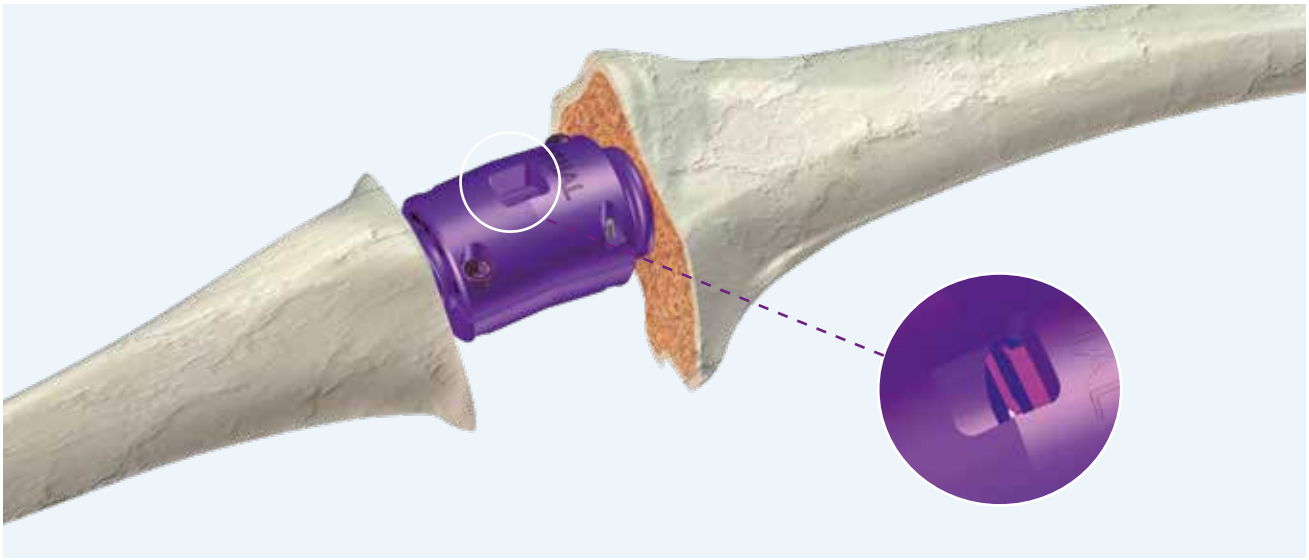


Figure 9: Trial nail position within Trial Spacer.

Trial nails for the optional expanded sets (18 mm diameter collared nails and 20 mm diameter non-collared nails) are available on request.

When the leg has the desired length, remove the trial components. Use the Extractor (Ref. GB90203) and the Slotted Hammer (Ref. AI00048) to remove the trial nails. To do this, screw the Extractor into the proximal thread of the nail (Figure 10).

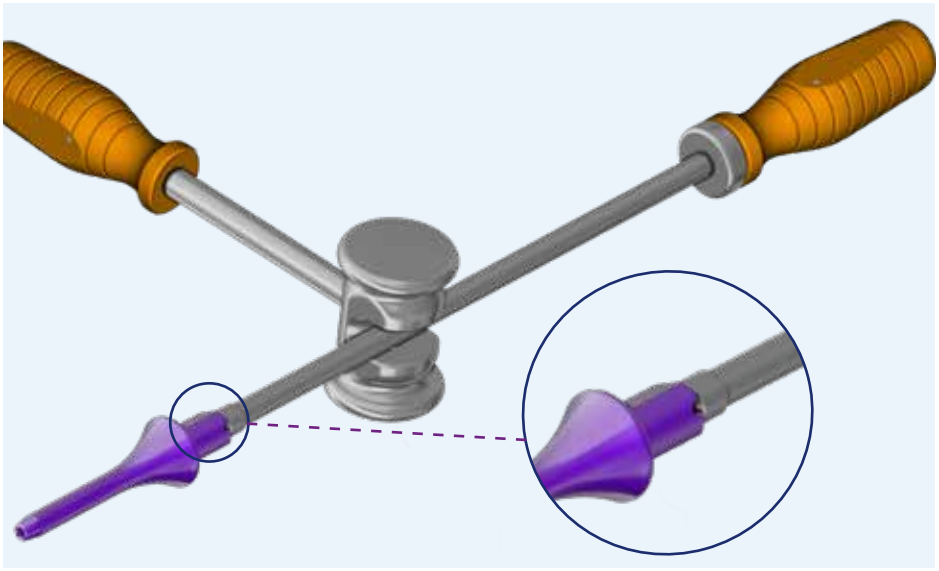


Figure 10: Removing the trial nails.

NOTE

Make sure that the Extractor (Ref. GB90203) is fully tightened and the contact surface is against the nail.

Caution

When removing the trial nail, make sure that the Extractor (Ref. GB90203) is in line with the trial nail to avoid excessive force on the thread of the Extractor.

4.4. Inserting the Nails

NOTE
Because of their funnel-shaped design, nails with a collar may cause a splitting or shattering effect (fissure) in the distal femur (condylar region) and the proximal tibia (plateau region) during implantation. Careful preparation of these bone regions, with the correct instrument and a proper cement mantle, if applicable are required.

Caution
Curved nails must only be used in the femur. Also, curved nails extend past the length of the Nail Guiding/Impacting Instrument (Ref. GA90100), their corresponding interlocking screws must be inserted under fluoroscopy without a guide.

The nails may be used with cemented or non-cemented anchoring.

4.4.1. Non-cemented

When using interlocking screws, the bore holes in the nail must be brought into the desired position. The Nail Guiding/Impacting Instrument (Ref. GA90100) with its "rib" is inserted into the "groove" at the proximal end of the nail and the adjusting screw is tightened until the nail is sitting securely on the guiding instrument. The nail can be inserted into the bone in the correct position. The distance holder on the underside of the Nail Guiding/Impacting Instrument indicates the maximum length to which the nail can be inserted into the bone.

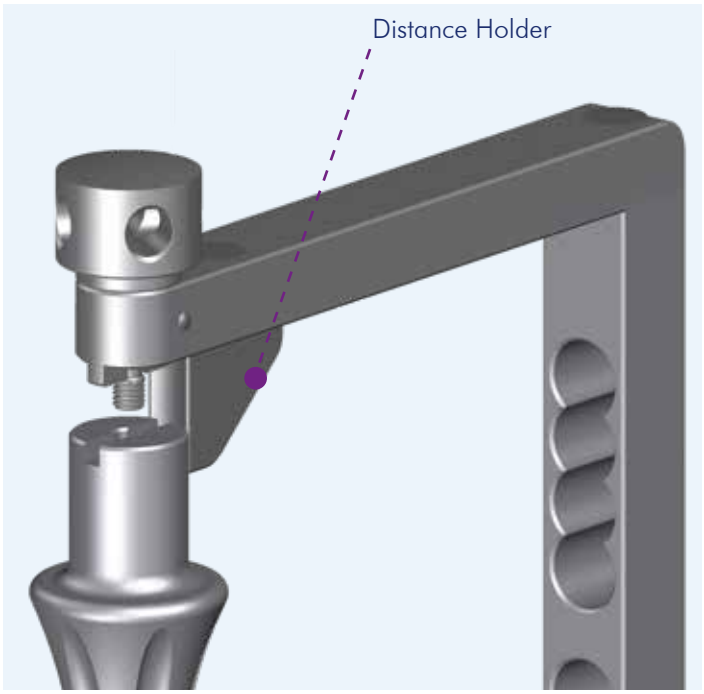


Figure 11: Nail Guiding/Impacting Instrument.

NOTE
Do not drive the nail any further in the bone. The nail's clamping area must be 18 mm in length for it to be clamped securely with the spacer!

NOTE
Make sure there is at least 5 cm of cortical bone contact, in order to ensure stable anchorage of the nail within the bone.

Locking the nails: Place the static interlocking screw first followed by the dynamic interlocking screw. Place the tissue Protection Sleeve (Ref. GB90101) into the Nail Guiding/Impacting Instrument drill hole corresponding to the nail length (note labeling on Nail Guiding/Impacting Instrument (Figure 12)). Use the tip of the Trocar (Ref. GB90102) to center-punch the drill hole. Remove the Trocar from the Protection Sleeve, and screw in the Drill Sleeve (Ref. GB90145).

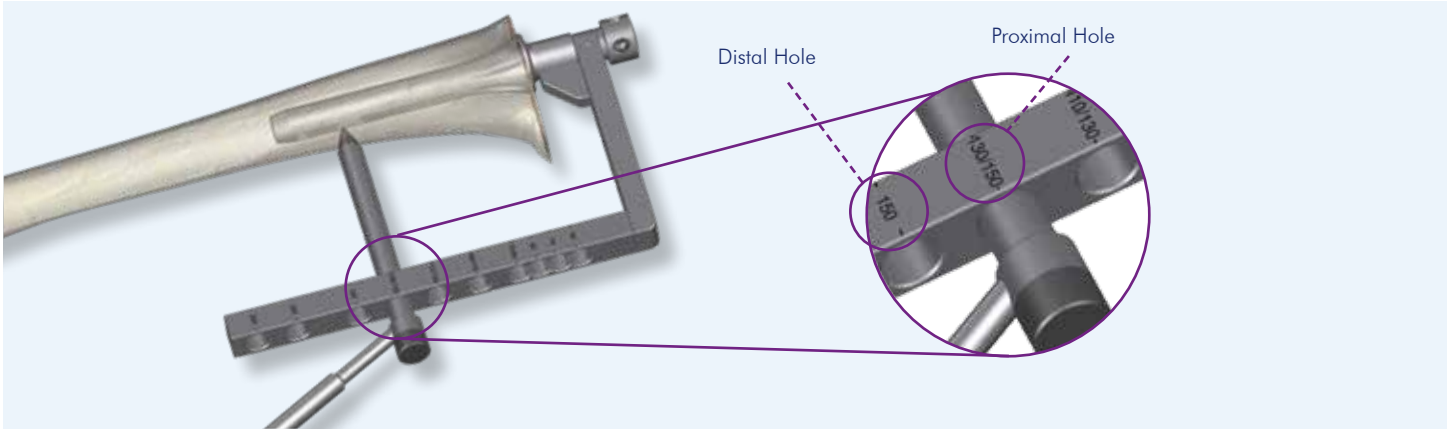


Figure 12: Distal and proximal holes for 150 mm nail.

Drill a bicortical locking hole using the DIA. 4.5 mm Drill with AO Connector (Ref. GB90245). Remove the Drill Sleeve (Ref. GB90145).

Then guide the Depth Gauge (Ref. AI00200) through the Protection Sleeve (Ref. GB90101) until it contacts the bone. Push the narrow rod of the Depth Gauge through the bone and hook it against the opposite cortical bone (Figure 13). Always round odd numbers to the next size up (e.g.: 43 mm measured - 44 mm interlocking screw).

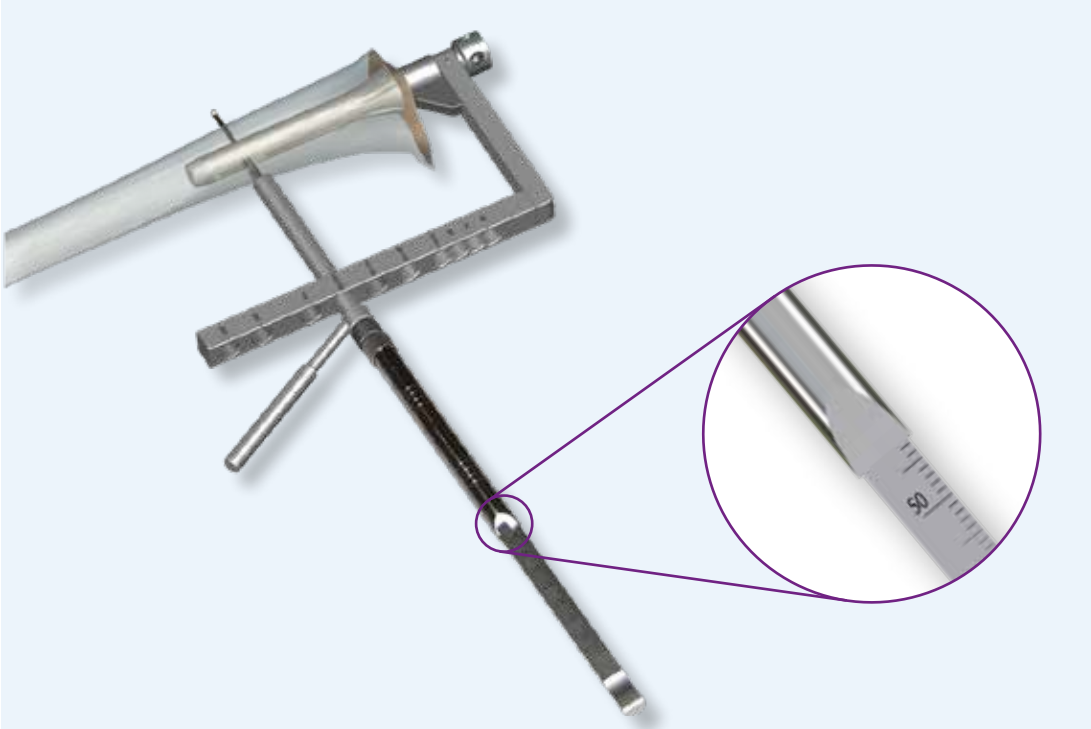


Figure 13: Depth Gauge.

Screwdrivers and drills with AO connection can also be used manually.

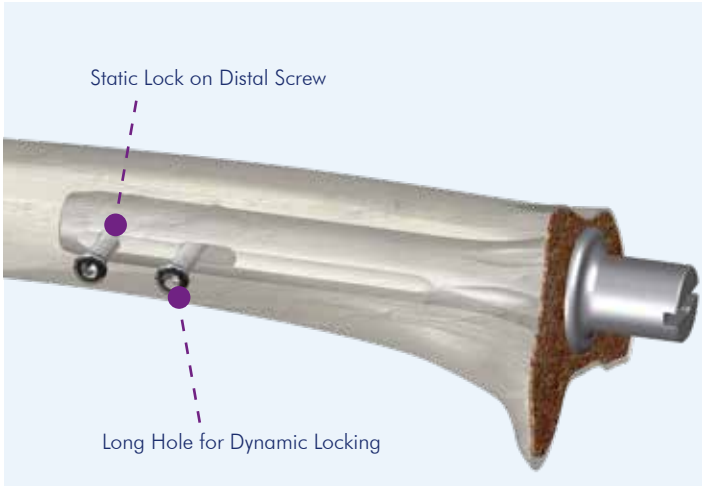


Figure 14: Locked nail.

Guide the correct interlocking screw through the Protection Sleeve (Ref. GB90101)and tighten it using the included Hex 3. 5 mm Screwdriver (Ref. AI00135) or Hex 3.5 mm Screwdriver with AO Connector (Ref. GA90023). The interlocking screws must be completely tightened. A bicortical anchoring is essential for a stable implant when using interlocking screws. All nails have two holes so that they can be double-locked (Figure 14). Once the holes have been placed and the screws have been inserted, the Nail Guiding/Impacting Instrument can be removed. Lock the first nail completely before locking the second nail.

After several weeks, the static lock can be removed to allow dynamization of the nail along the long hole.

4.4.2. Cemented

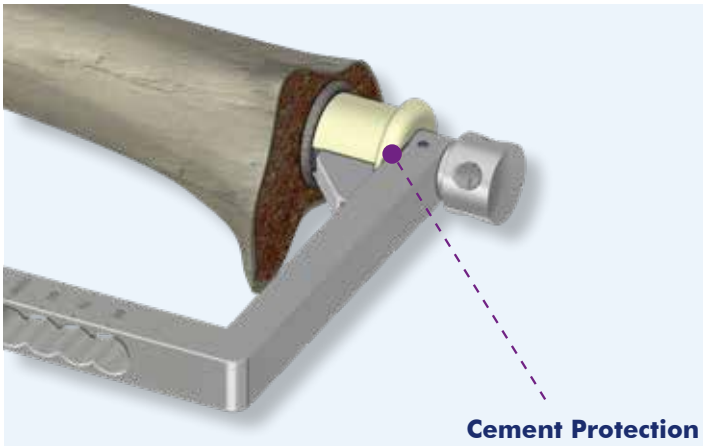
Ream the medullary cavity as specified in Tables 2 and 3 (Page 14) to ensure a 2 mm cement mantle (cement coating thickness of 1 mm on each side). The cement bed should be spread out evenly and be no thicker than 1-2 mm on each side. Place the Cement Protection Caps (Ref. GA90002 or GA90025) (Figure 15) on the nails before cementing and use a cement restrictor to ensure a proper cement mantle. The nails can be inserted into the bone directly, using the Cement Protection Caps (Ref. GA90002), or with the help of the Nail Guiding/Impacting Instrument (Ref. GA90100) together with the Cement Protection Caps (Ref. GA90025). After the nails have been inserted, remove the caps.

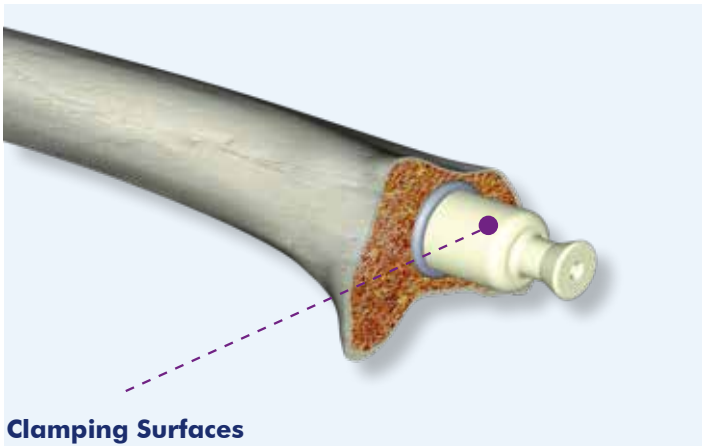
NOTE
Make sure there is at least 5 cm of cortical bone contact, in order to ensure stable anchorage of the nail within the bone cement.

NOTE
Do **not** additionally lock the nail after cementing.

Caution
(Not recommended) Interlocking of nails with cementation leads to:

- Loosening or breakage of the locking screw
- Loosening or breakage of the nail
- Breakage of the cement mantle
- Heat generation
- Breakage of the drill (drill in the instrument tray is not designed for use in bone cement) can occur.





Cement Protection for Clamping Surfaces

Figure 15: Nail cement protection.

The Impactor (Ref. GA90008) can be used if desired. The nail can be inserted into the bone up to the limit stop (Figure 16).

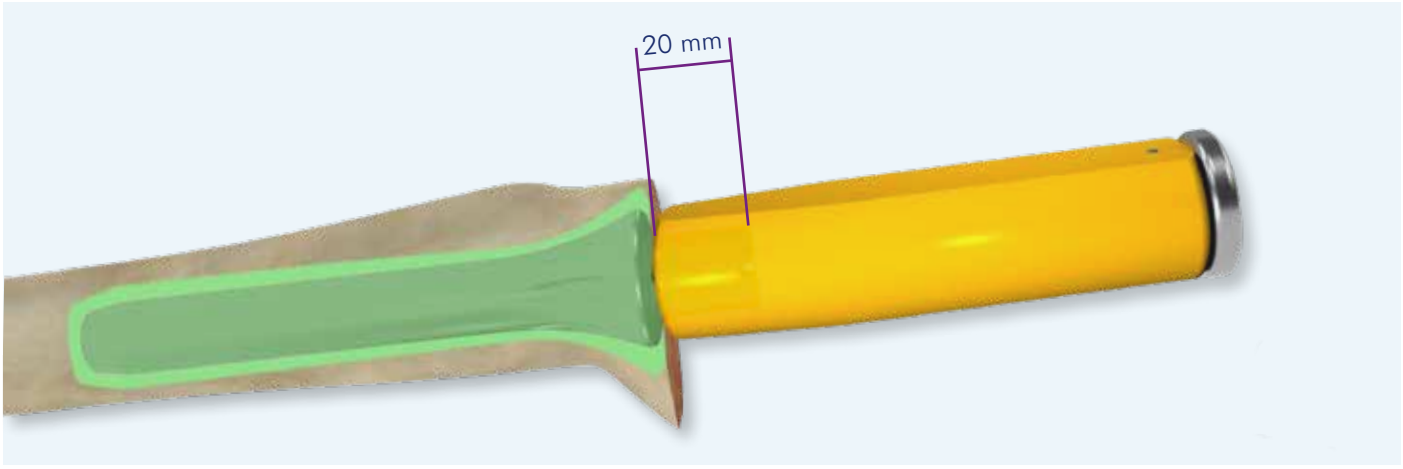


Figure 16: Use of the Impactor.

4.4.3. Curved Nails

The 250 mm and 300 mm curved nails are to be interlocked free-hand using fluoroscopy. The Nail Guiding/Impacting Instrument (Ref. GA90100) or the Impactor can only be used for the insertion process (Figure 17).

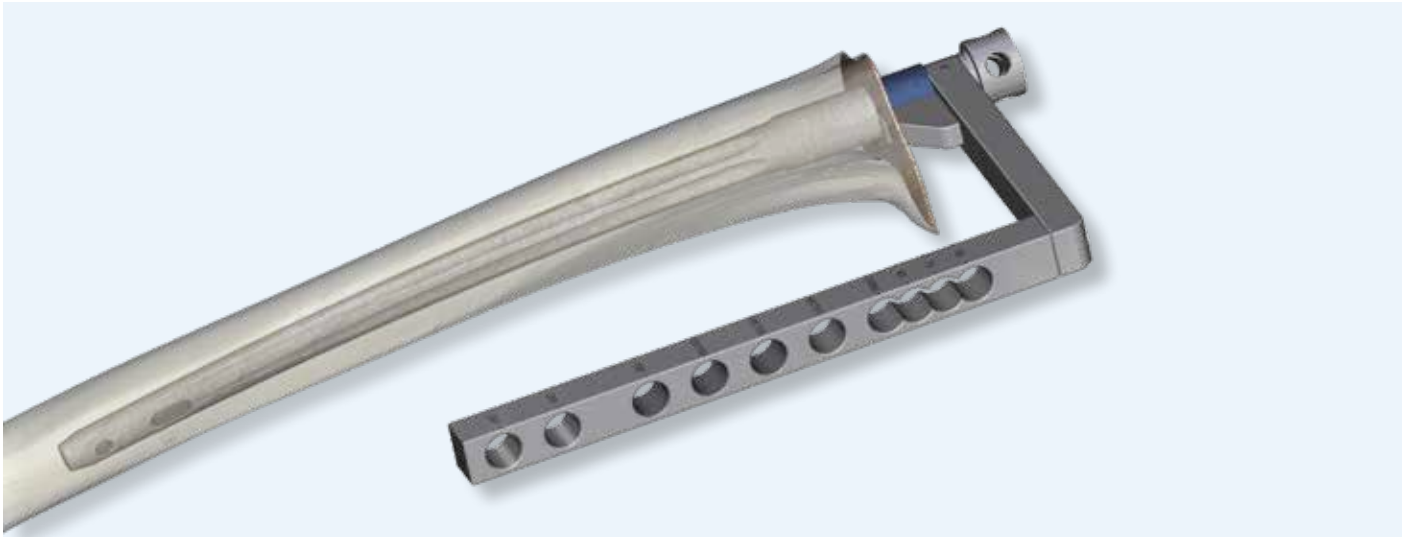


Figure 17: Inserting curved nails.

NOTE
Curved nails are only intended for use in the femur.

4.5. Inserting and Screwing of the Spacer

Warnings

Incorrect or improper assembly of implant. Risk of increased wear to implant! Risk of implant failure! Prior to assembling the spacer wash the clamping surface in order to completely remove all kinds of debris, including bone splinters, soft tissue parts, bone cement and others.

It is essential to ensure that the implant nails are clamped in the spacer at their minimum respective clamp lengths and the spacer is flush with the clamping areas of the nails.

The instructions for the assembling of the spacer with the spacer screws are to be followed exactly. All eight screws must be used for spacer assembly.

Use the distance holder during assembly to maintain the necessary gap between nail collar and spacer.

Do not allow nails to contact each other in spacer.

Use the guiding pins during assembly to ensure the spacer half-shells remain parallel to each other. When screwing in the guiding pins or spacer screws, be careful not to damage the spacer threads.

Foreign bodies (e.g. cement residues, tissue, bones) between implant components. Risk of injury due to implant failure. Thoroughly clean any foreign bodies from implant components.

To implant the Spacer (Ref. GA04041), put the lower Spacer half-shell into place underneath the nails. Note the nails have a minimum clamping length of 18 mm! Do not go below this minimum. The colored clamping area must be completely visible inside the Spacer. Screw four Guiding Pins (Ref. GA90003) into the outer holes. They serve as guides for inserting the upper Spacer half-shell. Propping the knee at a slight bend makes it easier to implant the Spacer.

Put a Distance Holder (Ref. GA90007) between the Spacer and each collared nail (Figure 18). It indicates the distance which will be necessary for implantation. The point on the Distance Holder is on the side facing away from the Spacer (Figure 19).

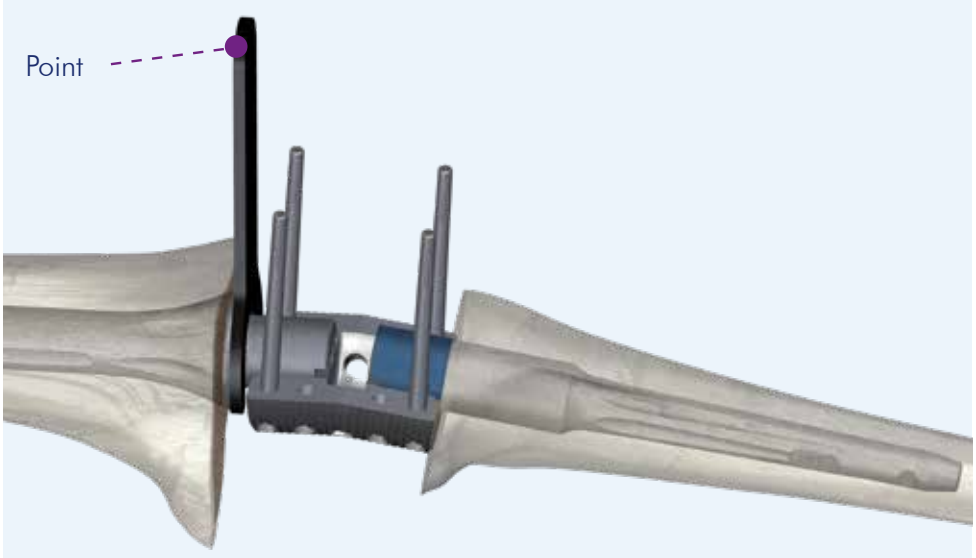
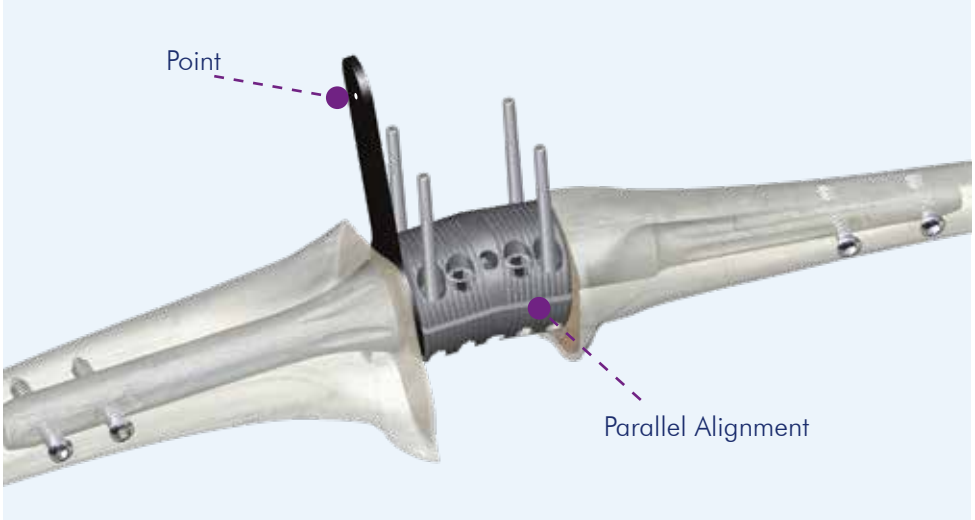


Figure 18: Using of the Distance Holder

NOTE
Before tightening the screws evenly, make sure that the two Spacer half-shells are parallel (same distance on both sides). Rotate the angled Spacer to set the joint's valgus or varus position if desired.



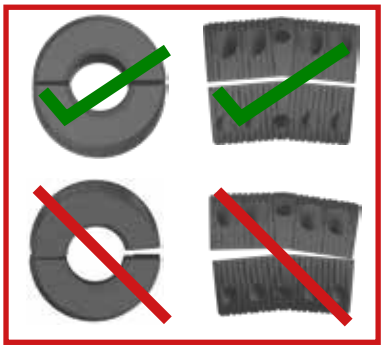


Figure 19: Space Alignment.

NOTE
To avoid tilting or misalignment of the clamping screws, ensure there is no tension on the system from soft tissue interference.

4.6. IMPORTANT INFORMATION: TIGHTENING THE CLAMPING SCREWS

Warning

Torque limiter not used or incorrectly used during implant assembly. Risk of increased wear to implant!

Risk of implant failure! Use the torque limiter during assembly and follow the sequence instructed for tightening the screws to ensure even and sufficient clamping of the spacers. Tighten all eight screws three times in the given order until the correct torque has been reached. When reaching the correct torque a "pop" sound is triggered.

The clamping screws must be tightened into their final position with the corresponding Torque Limiter (Ref. GA90026) in accordance with the scheme below, in order to ensure even Spacer (Ref. GA04041) clamping (Figure 20):

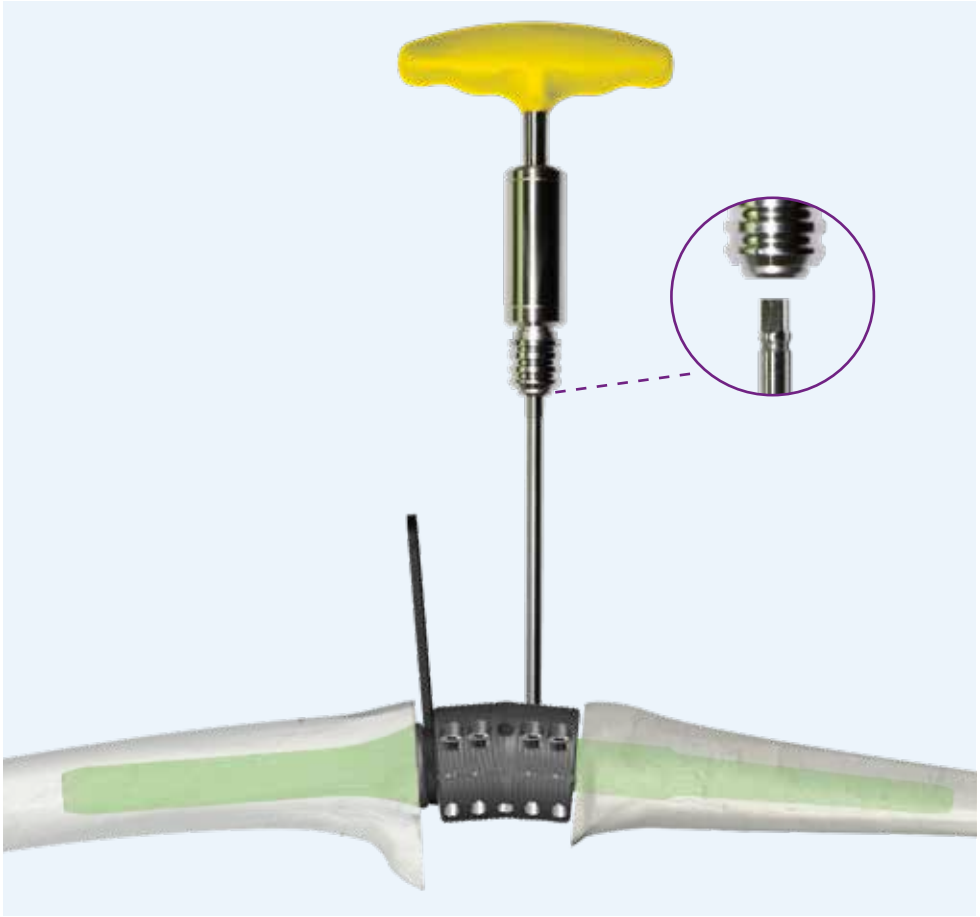


Figure 20: Using the Torque Limiter.

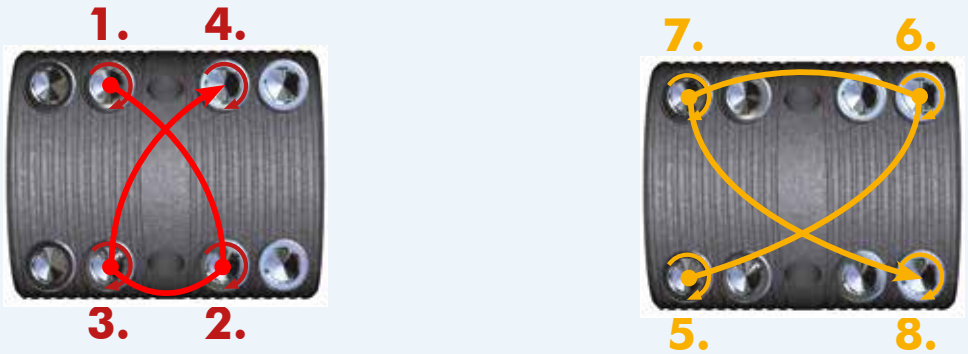


Figure 21: Sequence for tightening clamping screws.

The Torque Limiter consists of two parts: a T-handle (Ref. GA90026) and a Hex 5.0 mm Screwdriver with 1/4" connector (Ref. GA90024). Connect to one another with a 1/4" coupling. Starting on the inside with clamping screw 1, tighten the screws in order **crosswise** (see Figure 21). When reaching the correct torque a "pop" sound is triggered.

Tighten all eight screws **three times** in the order shown above until the correct torque has been reached.

4.7. Revision Surgery

NOTE
For explantation, please order the instrument trays (Ref. GA91006 and Ref. GA91005).

In the event that the OsteoBridge™ Intramedullary Knee Arthrodesis (IKA) needs to be revised, please order the instrument trays (Ref. GA91006 and Ref. GA91005). Start by removing all clamping screws from the Spacer (Figure 22) and then remove the upper and lower Spacer half-shells (Figure 23).

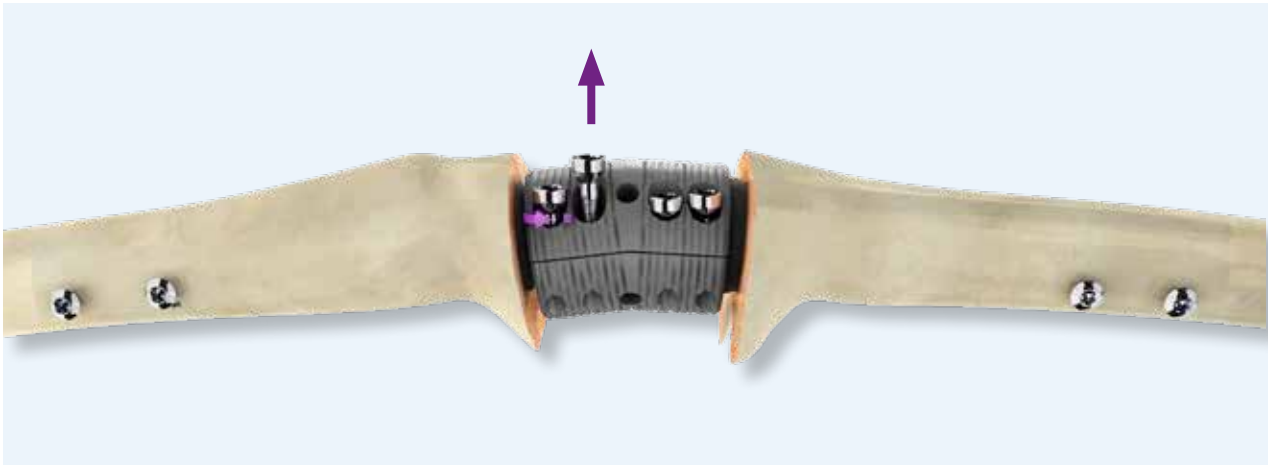


Figure 22: Removing the clamping screws from the Spacer.

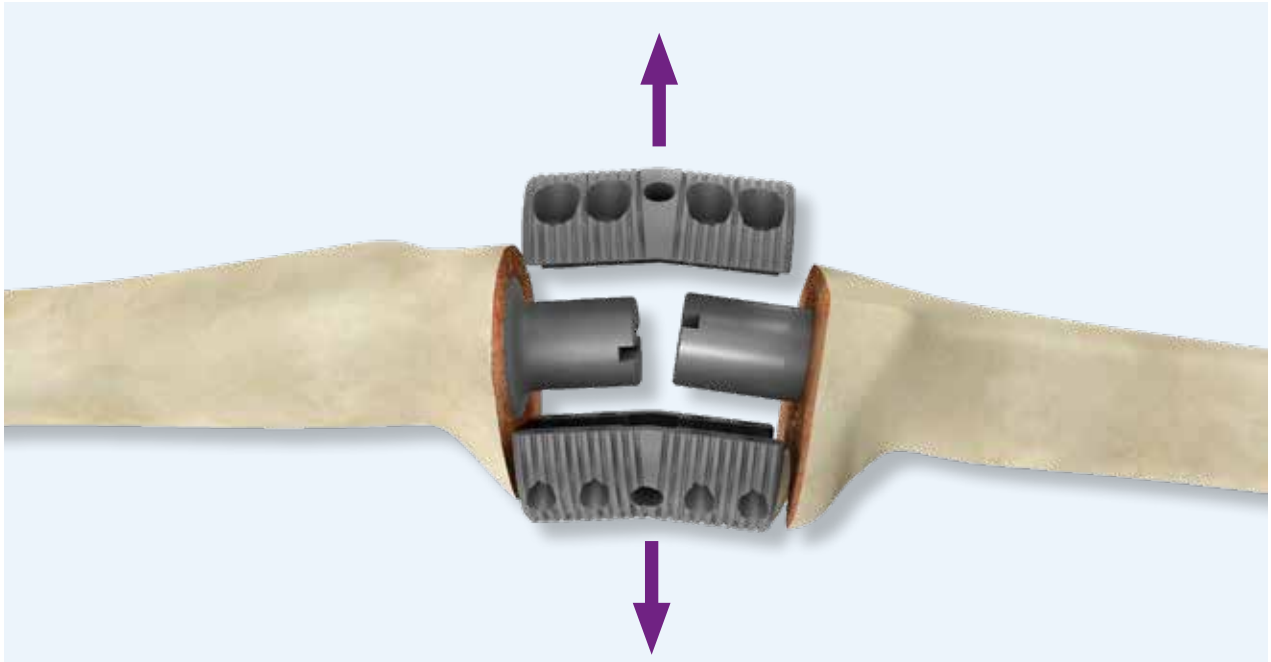


Figure 23 Removing the Spacer half-shell

Figure 24: Removing the interlocking screws.

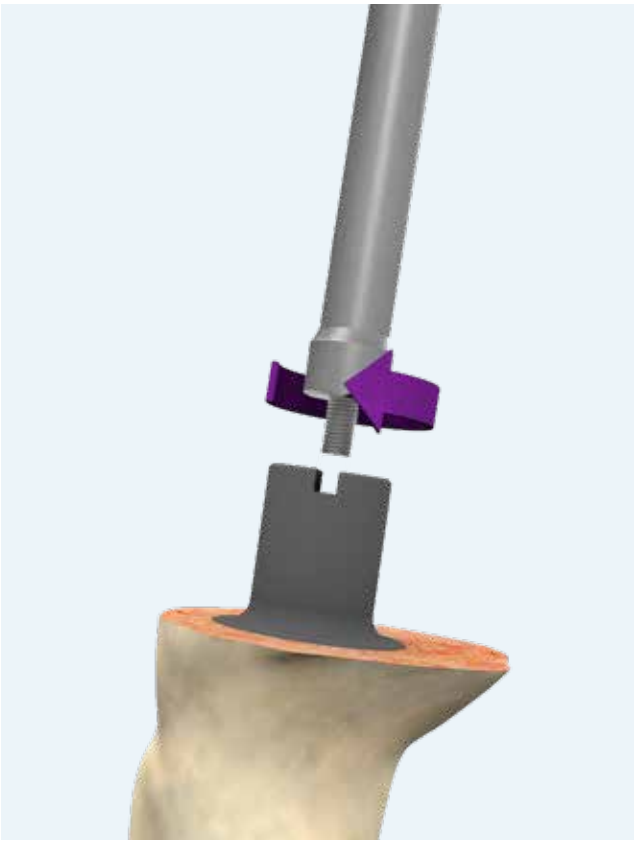


Figure 25: Screwing in the Extractor.

Remove interlocking screws if present (Figure 24). After that, screw the Extractor (Ref. GB90203) into each nail (Figure 25), and tap it out with the Slotted Hammer (Ref. AI00048) to remove it (Figure 26).

NOTE
Make sure that the Extractor (Ref. GB90203) is fully tightened and the contact surface is against the nail.

NOTE
Use only the implant Extractor (Ref. GB90203) to extract implanted nails.

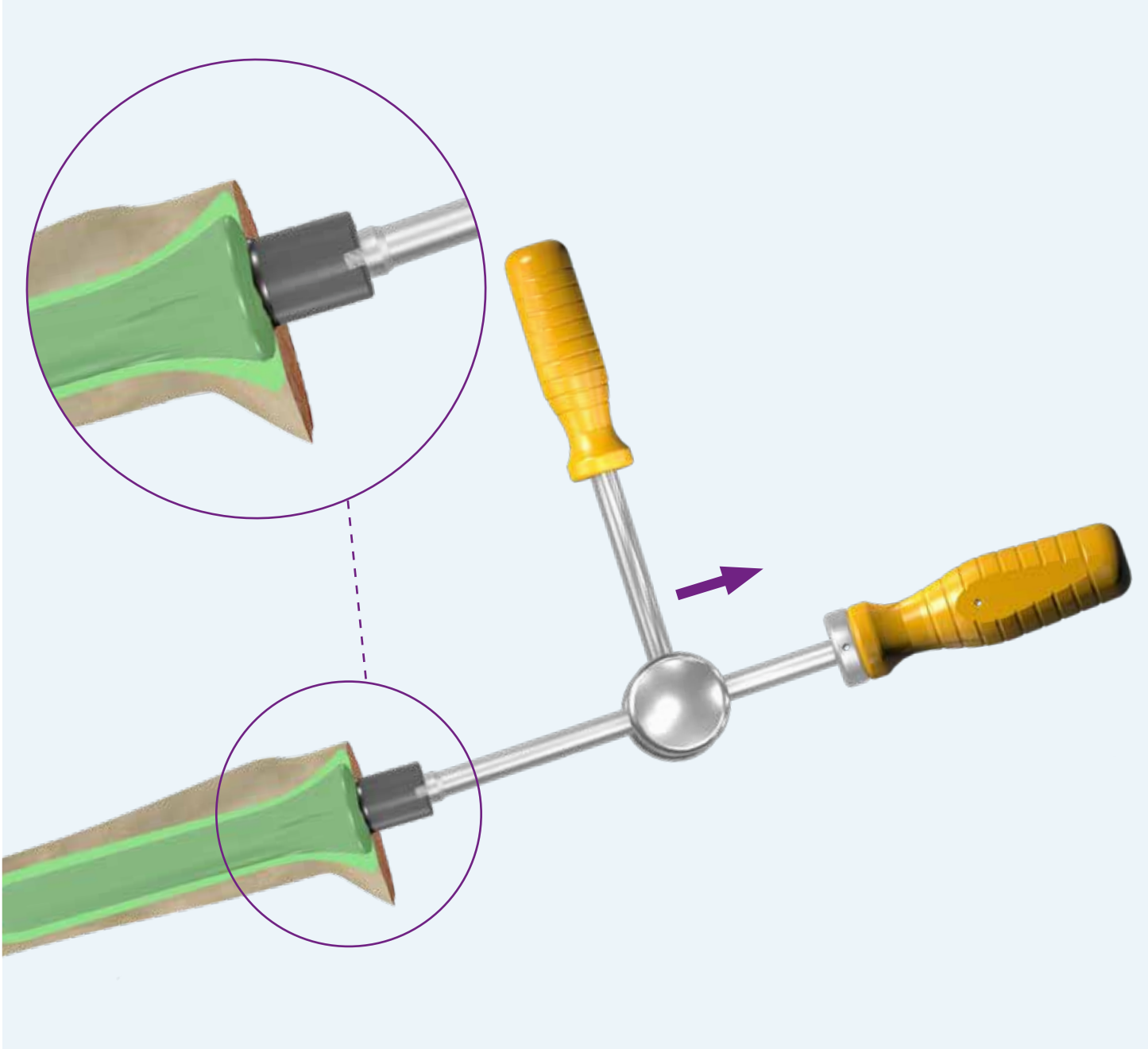


Figure 26: Extracting the Nails.

NOTE
When removing the nails, make sure that the Extractor (Ref. GB90203) is in line with the nail to avoid excessive force on the thread of the Extractor.

5. Ordering Information

5.1. Implants

Collared Nail, Sterile

Length (mm)	DIA. (mm)	DIA. 10	DIA. 12	DIA. 14	DIA. 16	DIA. 18
	L = 130	GA11013	GA11213	GA11413	GA11613	GA11813
	L = 150	GA11015	GA11215	GA11415	GA11615	GA11815
	L = 200	-	GA11220	GA11420	GA11620	GA11820

Interlocking Screws, Sterile

Diameter 5 mm

Ref.	Length
GB35020S	20 mm
GB35022S	22 mm
GB35024S	24 mm
GB35026S	26 mm
GB35028S	28 mm
GB35030S	30 mm
GB35032S	32 mm

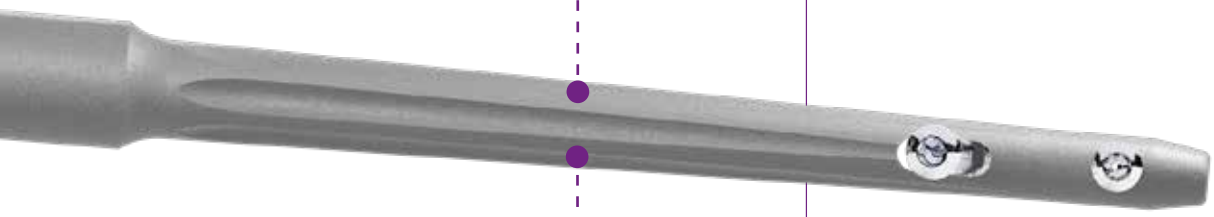
Ref.	Length
GB35034S	34 mm
GB35036S	36 mm
GB35038S	38 mm
GB35040S	40 mm
GB35042S	42 mm
GB35044S	44 mm
GB35046S	46 mm

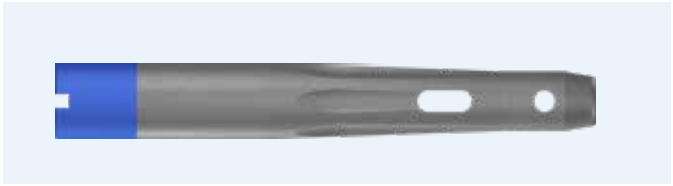
Ref.	Length
GB35048S	48 mm
GB35050S	50 mm
GB35052S	52 mm
GB35054S	54 mm
GB35056S	56 mm
GB35060S	60 mm
GB35065S	65 mm

Spacer angled, Sterile

Diameter 40 mm, Angle 10°

Ref.	Length
GA04041	50 mm





Non-Collared Nail, Sterile

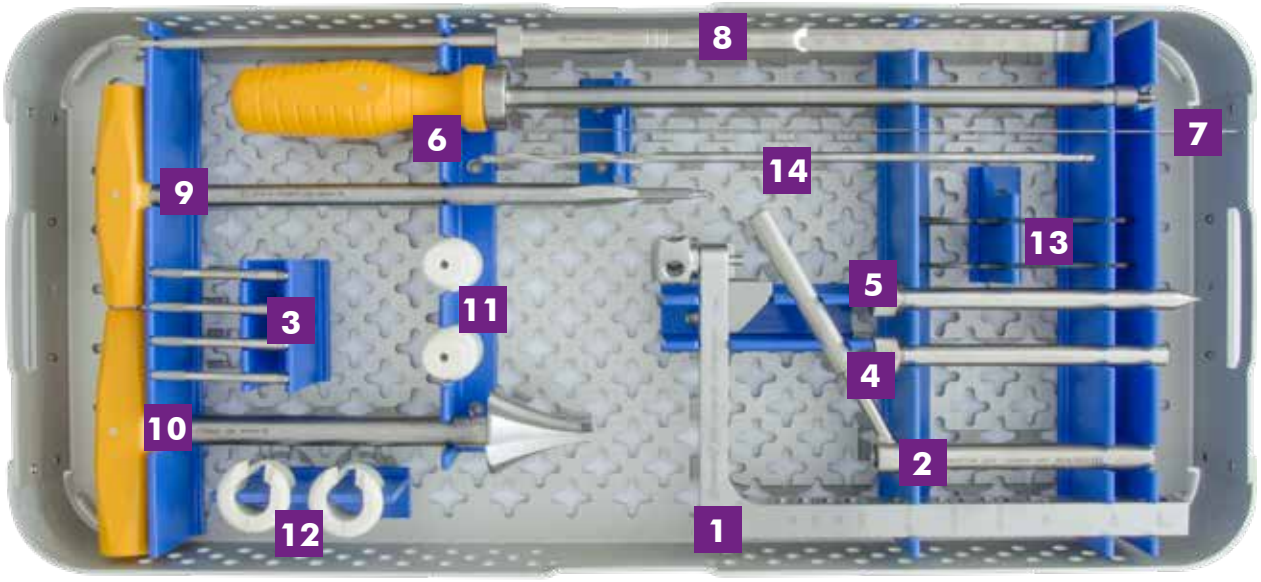
Length (mm)	DIA. (mm)	DIA. 14	DIA. 16	DIA. 18	DIA. 20
	L = 130	GA21413	GA21613	GA21813	-
	L = 150	GA21415	GA21615	GA21815	GA22015
	L = 200	GA21420	GA21620	GA21820	GA22020

Non-Collared Nail, Curved, Sterile

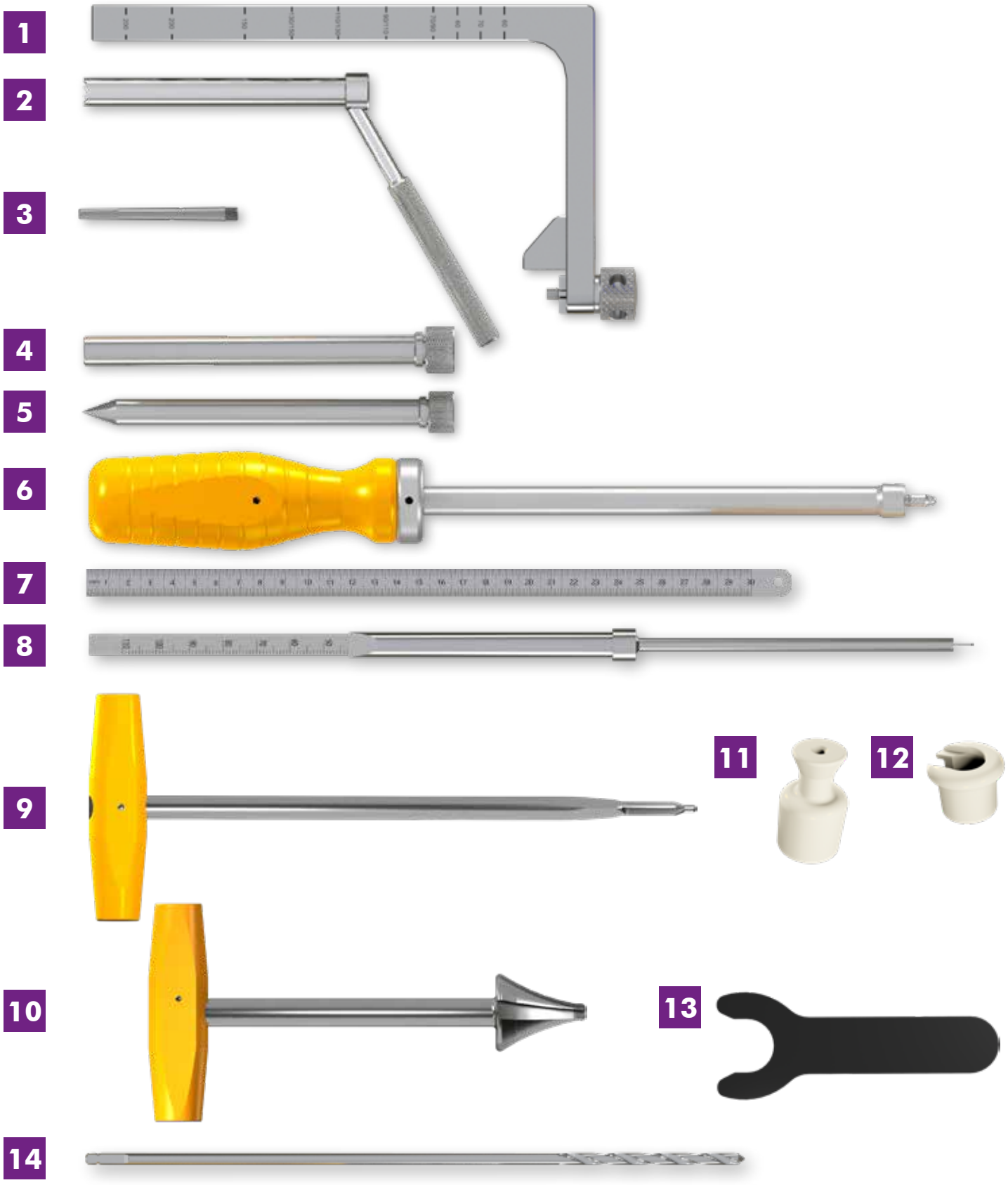
Length (mm)	DIA. (mm)	DIA. 14	DIA. 16	DIA. 18	DIA. 20
	L = 250	GA21425	GA21625	GA21825	GA22025
	L = 300	GA21430	GA21630	GA21830	GA22030

5.2. Instruments

Ref.	Description
GA91006	**OsteoBridge™ Intramedullary Knee Arthrodesis (IKA) Instrument Tray 1/2**



No.	Ref.	Description	Qty.
1	GA90100	Nail Guiding/Impacting Instrument	1
2	GB90101	Protection Sleeve	1
3	GA90003	Guiding Pin	4
4	GB90145	Drill Sleeve for DIA. 4.5 mm drill	1
5	GB90102	Trocar	1
6	GB90203	Extractor	1
7	AI90300	300 mm Steel Ruler	1
8	AI00200	Depth Gauge	1
9	GA90020	Dia. 6.0 mm Manual Awl	1
10	GA90021	Reamer	1
11	GA90002	Cement Protection Cap	2
12	GA90025	Cement Protection Cap for use with Nail Guiding/Impacting Instrument	2
13	GA90007	Distance Holder	2
14	GB90245	DIA. 4.5 mm Drill with AO connector for DIA. 5.0 mm Interlocking Screws	2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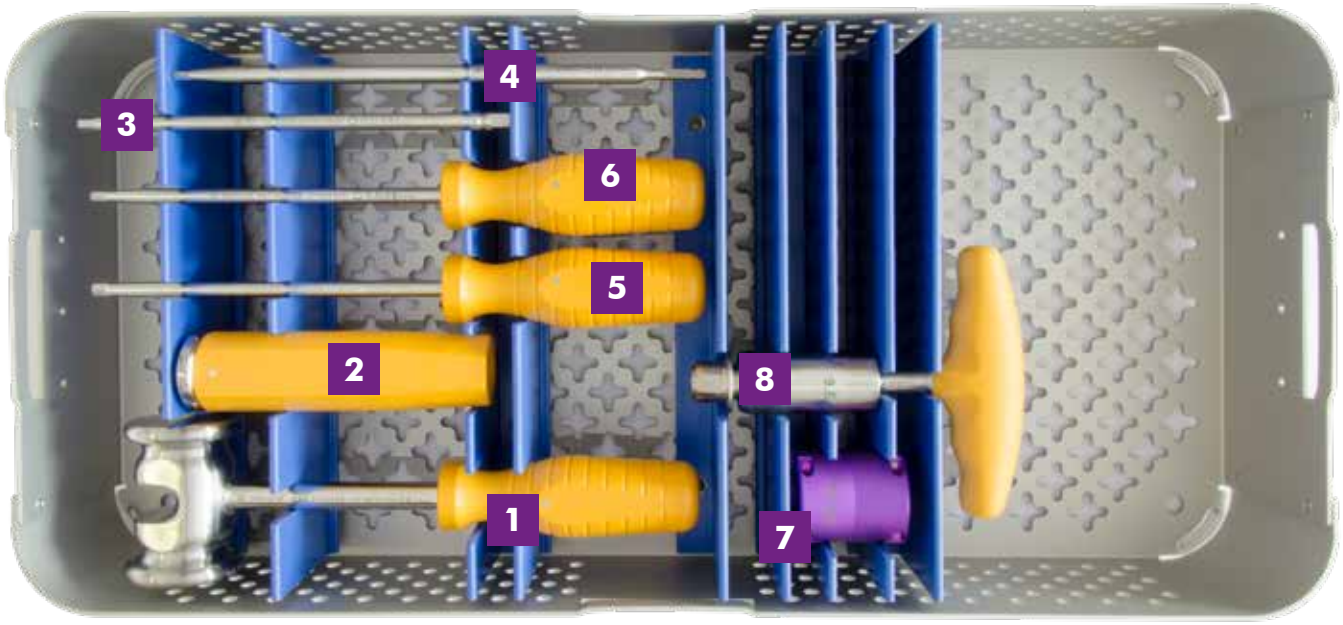
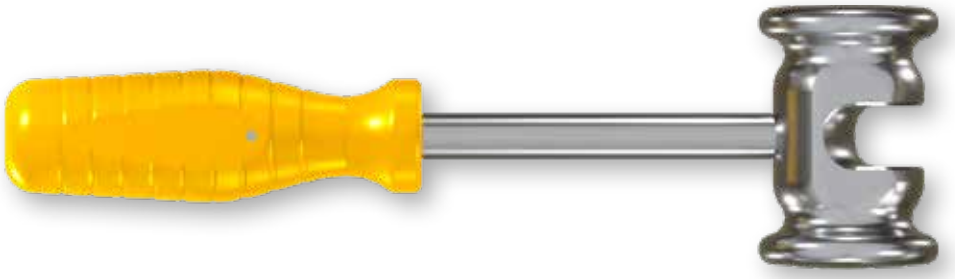
Ref.	Description
GA91005	**OsteoBridge™ Intramedullary Knee Arthrodesis (IKA) Instrument Tray 2/2**



No.	Ref.	Description	Qty.
1	AI00048	Slotted Hammer	1
2	GA90008	Impactor	1
3	GA90024	Hex 5.0 mm Screwdriver with 1/4“Connector for DIA. 5.0 mm Clamping Screws	1
4	GA90023	Hex 3.5 mm Screwdriver with AO Connector for DIA. 5.0 mm Interlocking Screws	1
5	GA90009	Hex 5.0 mm Screwdriver for DIA. 5.0 mm Clamping Screws	1
6	AI00135	Hex 3.5 mm Screwdriver	1
7	GA54041	Trial Spacer DIA. 40 mm, 10°, Length 50 mm	1
8	GA90026	Torque Limiter with T-handle and 1/4‘‘Connector 9.5 Nm for DIA. 5.0 mm, Clamping Screws	1

1



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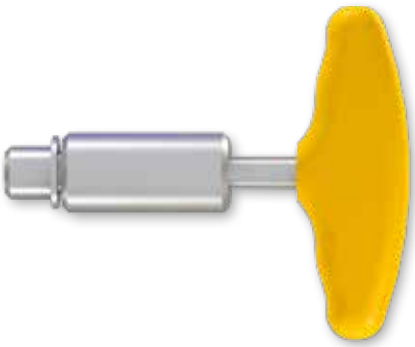
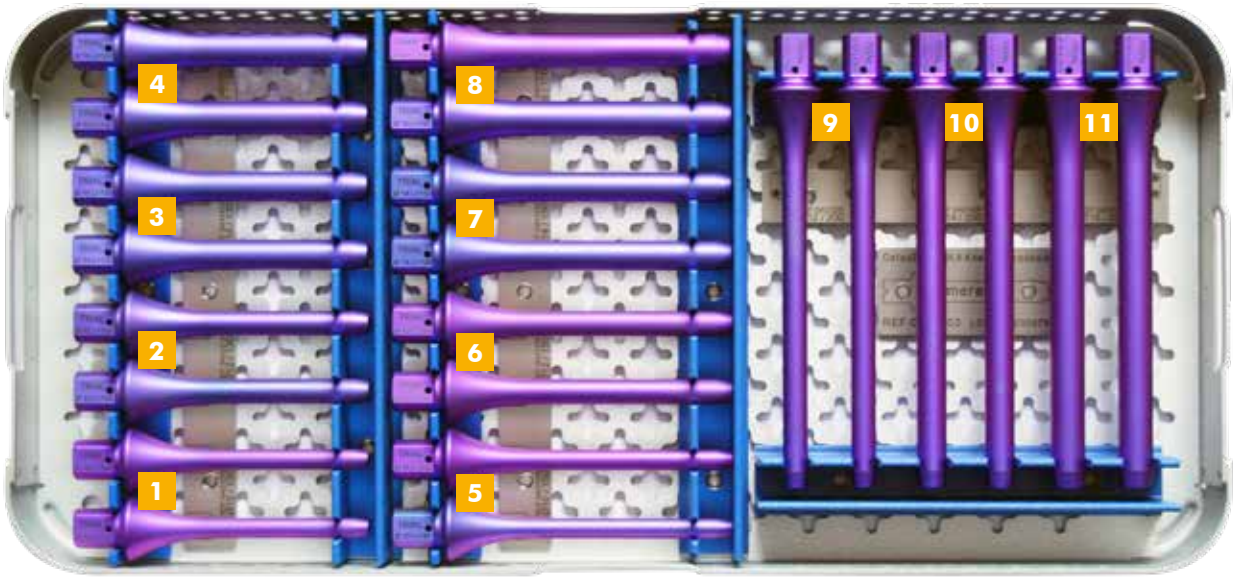


5.3. Trial Nails

Ref.	Description
GA91003	**Trial Nail Tray 1 (collared nails)** Trial Nail Tray with 2 Trial Nails with collar each size



No.	Diameter/ Length	130 mm	150 mm	200 mm
1	10/30	GA31013	-	-
2	12/30	GA31213	-	-
3	14/30	GA31413	-	-
4	16/30	GA31613	-	-
5	10/30	-	GA31015	-
6	12/30	-	GA31215	-
7	14/30	-	GA31415	-
8	16/30	-	GA31615	-
9	12/30	-	-	GA31220
10	14/30	-	-	GA31420
11	16/30	-	-	GA31620

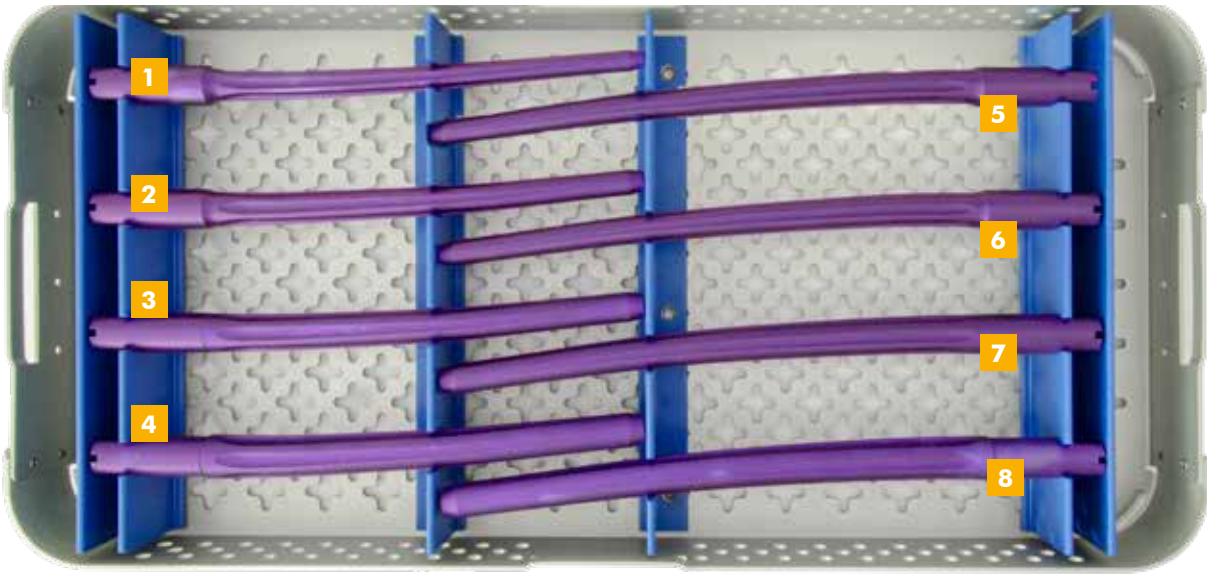
Trial nails with DIA. 18 mm are available on request				
No.	**Diameter/ Length**	**130 mm**	**150 mm**	**200 mm**
-	18/30	GA31813	-	-
-	18/30	-	GA31815	-
-	18/30	-	-	GA31820

Ref.	Description
GA91004	**Trial Nail Tray 2 (non-collared nails)** Trial Nail Tray with 2 Trial Nails without collar each size

No.	Diameter/ Length	130 mm	150 mm	200 mm
1	14	GA41413	-	-
2	16	GA41613	-	-
3	18	GA41813	-	-
4	14	-	GA41415	-
5	16	-	GA41615	-
6	18	-	GA41815	-
7	14	-	-	GA41420
8	16	-	-	GA41620
9	18	-	-	GA41820

Trial nails with DIA. 18 mm are available on request			
No.	**Diameter/ Length**	**150 mm**	**200 mm**
-	20	GA42015	-
-	20	-	GA42020

Ref.	Description
GA91009	**Trial Nail Tray 3 (non-collared nails, curved)**



No.	Diameter/ Length	250 mm	300 mm
1	14	GA41425	-
2	16	GA41625	-
3	18	GA41825	-
4	20	GA42025	-
5	14	-	GA41430
6	16	-	GA41630
7	18	-	GA41830
8	20	-	GA42030

5.4. References

Begkas, D., A. Pastroudis, D. L. Katsenis and S. Tsamados (2015). "Management of a distal femoral non-union with coexisting failure of the knee extensor mechanism using OsteoBridge knee-arthrodesis system -- A case report." Med Pregl 68 (11-12): 405-409.

Flesch, I. and C. Bahrs (2011). Experiences with cemented and uncemented nails in knee arthrodesis compared to arthrodesis with plates or fixateur extern. EBJIS. Copenhagen, Denmark.

Wetzel, R. (2010). Short term results of a new modular spacer arthrodesis in large bone defects after failed knee arthroplasty. EBJIS. Heidelberg, Germany.

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HDB0070-001-0320 (Date of Issue 23.06.2020) Technical information subject to change, information provided without guarantee, images: Merete GmbH

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