ANA NOVA

ANATOMICA NOVA HIP ENDOPROSTHESIS

Alpha Stem proxy

SURGICAL TECHNIQUE

This surgical technique is only intended for healthcare professionals, in particular doctors.
The information on the products and/or procedures contained in the brochure does not constitute medical advice or a medical recommendation. Each patient must be provided with an individual explanation and consultation, as the information contained in this brochure does not contain diagnostic or therapeutic information about specific medical cases.

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The ANA.NOVA Alpha Stem proxy by ImplanTec

ANA NOVA

The modular hip system for the individual needs of patients.

Over the last century, total hip arthroplasty (THA) has undergone several paradigm-shifting innovations. As a company with four decades of history in developing and distributing innovative hip joint prostheses, ImplanTec, based in Mödling, Austria, a medical device manufacturer with a number of production sites in Austria and Germany, plays an important role in providing the latest advances to orthopaedic patients and surgeons in the DACH region of Europe. ImplanTec is committed to utilising its extensive experience, dynamic innovative spirit and rigorous quality assurance processes to provide technology solutions that ensure the best patient outcomes and highest degree of patient mobility.

THE MODULAR HIP SYSTEM


Hybrid Cup


Alpha Cup


Ceramic insert

Miradur insert


Miradur Dysplasia insert

PE Insert

PE Dysplasia Insert


Ceramic ball head


Ceramic ball head BIOLOX OPTION


Alpha Stem proxy


Alpha Stem


Mini Stem


SL-Complete Stem


Solitär Stem


Revision Stem

The ANA.NOVA success story

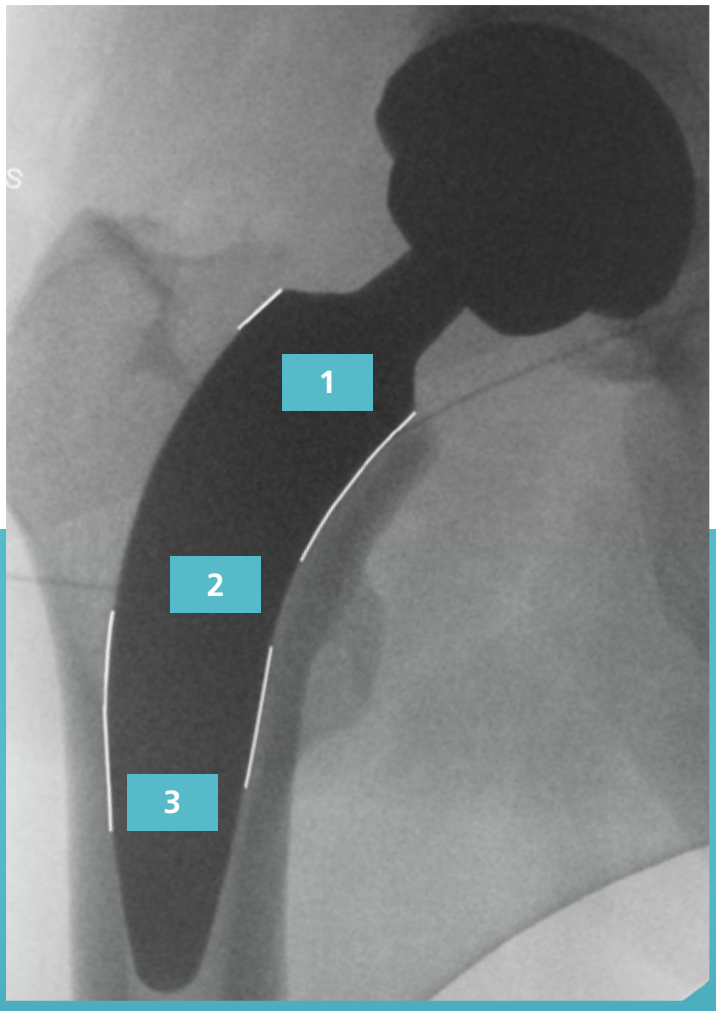
The cementless ANA.NOVA hip system by ImplanTec comprises primary hip stems, a revision stem, two press-fit cups, including the ANA.NOVA Hybrid Cup with unique stabilising elements, and all the common options for tribological pairing. This range of implants is supported by ImplanTec's own instruments, which are optimised for different surgical techniques and support the surgeon in selecting the implant and implantation procedure that best suits the patient's individual needs. The ANA.NOVA product range has been developed with years of unique patient requirements in mind, reducing the initial assessment of patient factors and maximising surgical precision to achieve the best clinical outcomes. A more precise and intuitive procedure leads to a faster post-operative rehabilitation phase, which in turn enables more efficient reintegration into daily life.

The ANA.NOVA Alpha Stem proxy

The ANA.NOVA Alpha Stem proxy is a cementless short stem that optimally reconstructs the patient's anatomical conditions and can be used when the metaphyseal bone has a secure load-bearing capacity. The implants are intended for use in people who have finished growing. There is no general weight limit. Its curved, triple-conical and trapezoidal cross-section ensures controlled, rotationally stable anchoring in the metaphyseal femur region and thus optimum proximal application of force.
The stem design with customised instruments enables arc-shaped, bone-preserving and soft tissue-preserving insertion, making it ideal for all minimally invasive surgical techniques.
The biomechanical advantage of this new, metaphyseal anchoring arises from the proximal application of force and the simultaneous reduction of stress-shielding, which is known as the phenomenon of emphasised diaphyseal anchoring.

The ANA.NOVA Alpha Stem proxy extends the ANA.NOVA hip system with its metaphyseal anchoring and is the ideal alternative and supplement to the ANA.NOVA Alpha Stem.

The high level of acceptance and widespread use confirm this concept.



BIOLOGICAL ANCHORING

The ANA.NOVA Alpha Stem proxy is a short stem with epi-metaphyseal anchoring with maximum preservation of the bone substance and the pelvitrochanteric musculature. This anchoring takes place in three zones:

1. **the epiphyseal zone at the femoral neck,**
2. **the proximal metaphyseal zone between the calcar and lateral corticalis (lateral flare)**
3. **the distal conical metaphyseal zone.**

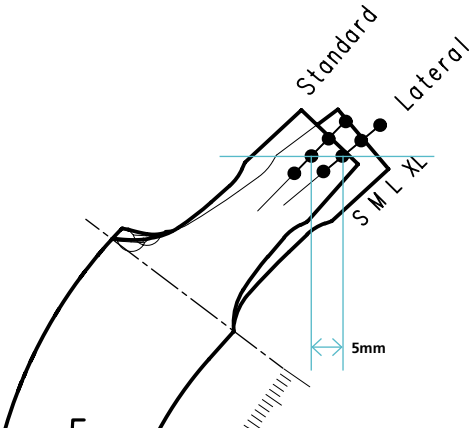
Due to this new, multi-point fixation in the proximal, cortical bone, conventional diaphyseal anchoring can be dispensed with in the ANA.NOVA Alpha Stem proxy.

PROVEN DESIGN

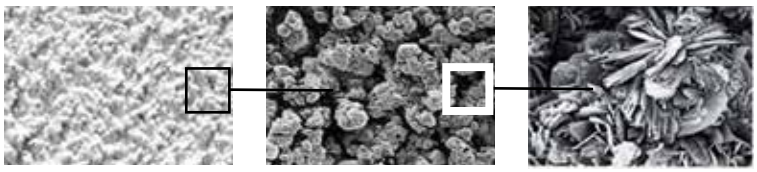
The main fixation zone for the ANA.NOVA Alpha Stem proxy lies between the medial calcar and lateral cortex due to its design with the triple-conical, trapezoidal cross-section.

TECHNICAL FEATURES

+ **High-strength forged titanium alloy (Ti6Al4V) as per ISO 5832-3**
+ **Triple-conical stem with trapezoidal cross-section**
+ **Cone 12/14**
+ **2 stem designs**
  standard and lateralised (+5mm)
+ **Polished distal stem tip - to prevent distal osteointegration and thus minimise femoral thigh pain**
+ **Maximum preservation of the bone substance and the pelvitrochanteric musculature.**
+ **Optimally suited for femoral neck angles from 115° to 140°**
+ **Polished prosthesis neck**
+ **Precise instrument for flexible surgical technique**



Macro-structure due to titanium plasma coating



TPS/BONIT

Accelerated osteointegration through full-surface, bioactive calcium phosphate coating (BONIT)

MODERN SURFACE TECHNOLOGY

The surface of the ANA.NOVA Alpha Stem proxy ensures excellent osteointegration due to the biocompatible titanium alloy and the rough titanium plasma coating. In addition, a 15µm microcrystalline calcium phosphate coating (BONIT) reinforces and accelerates osteointegration, especially in the initial post-operative phase. BONIT is applied electrochemically and essentially consists of nanocrystalline hydroxyapatite (HA).

Indications

+ Advanced osteoarthritis of the hip joint due to degenerative and post-traumatic changes or rheumatoid arthritis
+ Fracture or avascular necrosis of the femoral head
+ After-effects of previous operations, e.g. osteosynthesis, joint reconstruction, arthrodesis, hemiarthroplasty or total hip endoprosthesis

Contraindications

- Acute or chronic infections, local or systemic
- Serious muscle, nerve or vascular diseases that jeopardise the affected extremity
- Lack of bone substance or poor bone quality that jeopardises the stable fit of the prosthesis
- Any concomitant disease that may jeopardise the function of the implant
- Revision with extensive bone defects

Patients with osteoporosis and massive deformities of the proximal femur in the sense of coxa vara and valga should only be treated with suitable conventional prostheses. Since femoral neck anchoring is an essential component for securing rotation, the Alpha Stem proxy is not indicated in cases of undeveloped (e.g. massive dysplasia) and deficient (e.g. non-existent, deformed or fractured) femoral necks. This also applies to an unsecured load-bearing metaphyseal bone.

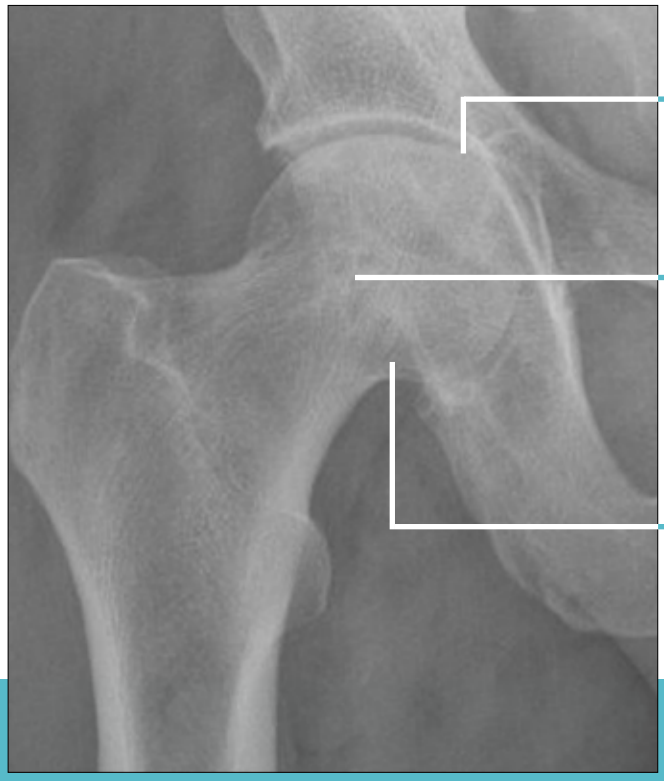
Planning of the cup position

Pre-operative planning begins with a pelvic overview image taken in the anteroposterior beam path. As an aid, vertical and horizontal auxiliary lines are drawn in, which serve as a guide and can shed light on any corrections that are necessary.

In a first step, the size and positioning of the artificial hip cup is selected. This depends on the centre of rotation and the anatomical and bony situation.

To determine the required size, the ANA.NOVA Hybrid Cups and ANA.NOVA Alpha Cups are available with X-ray templates in all sizes and for ball heads with diameters of 28mm, 32mm, 36mm and 40mm.

The determined cup position is compared with the anatomical cup entry site. For the rest of the planning process, it is important to clearly mark the centre of rotation of the cup on the X-ray image.



The X-ray template is moved until the contours of the template of the cup implant and the natural acetabulum match or slightly overlap.

The horizontal line of the centre of the femoral head on the contralateral side is used as a guide for the centre of rotation of the cup.

The marked inclination range on the X-ray template (45° +/- 5°) is parallel to the horizontal auxiliary line.

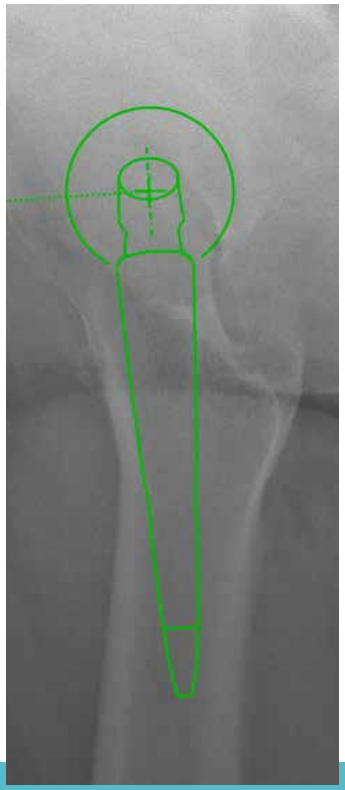
For further information on implantation of the hip cup, please refer to the surgical techniques for the ANA.NOVA Hybrid Cup, ref. no. 860105 and ANA.NOVA Alpha Cup, ref. no. 860106.

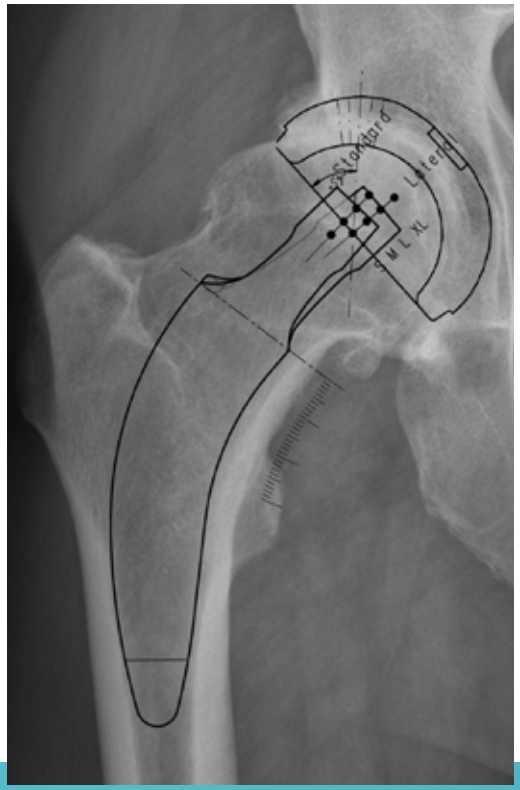
Planning of the ANA.NOVA Alpha Stem proxy position

The correct prosthesis size is planned using the X-ray template. X-ray templates with a magnification factor of 1.15:1 are also available digitally for the ANA.NOVA Alpha Stem proxy. The stem size that best achieves cortical anchoring is selected.

Since the femoral neck is an essential biological anchoring component in short stems, planning the required stem size and the resulting femoral neck resection plane is of crucial importance!

Measurements from the lesser trochanter to the resection plane or to the end of the stem taper are used to determine the correct position of the resection plane and the implant position.





1. Selection of the neck or ball head centre
which best corresponds to the planned cup centre

3. Determination of the resection height
The dotted line, which indicates the end of the rasp serration or the end of the anchoring of the ANA.NOVA Alpha Stem proxy, serves as an auxiliary line.

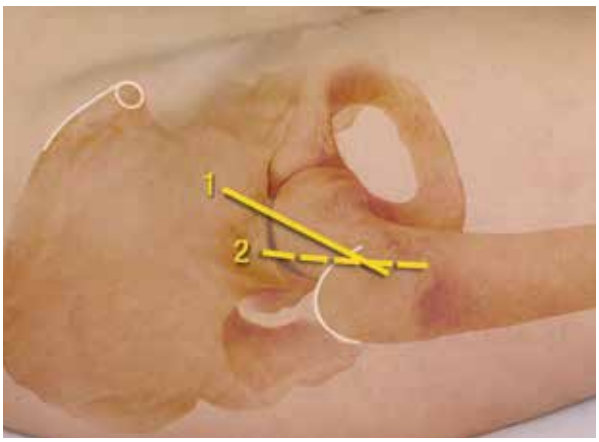
2. Cortical anchoring
The stem size that best achieves proximal cortical triple anchoring is selected.

PLEASE NOTE

The axial planning check is only intended for guidance, not for determining the size. The difference in perspective between the axial X-ray image and the X-ray template is problematic (see image). Axial planning must be taken into account, particularly in the case of severe femoral curvatures, as it often limits the stem size in this case.

Surgical approach

The ANA.NOVA Alpha stem proxy is particularly suitable for minimally invasive antero-lateral and anterior approach. Focus is on protecting the muscle attachments and bone substance. The most common methods for atraumatic "minimally invasive" approach in Europe include:



1 **Modified Smith-Peterson anterior approach**

2 **Modified Watson-Jones anterolateral approach**

These form the basis for instrument development and the surgical technique described.

Implantation of the cup

Implantation is carried out according to general guidelines
(see Surgical techniques
ANA.NOVA Hybrid Cup, lit. no. 860105,
ANA.NOVA Alpha Cup, lit. no. 860106).

Implantation of the stem

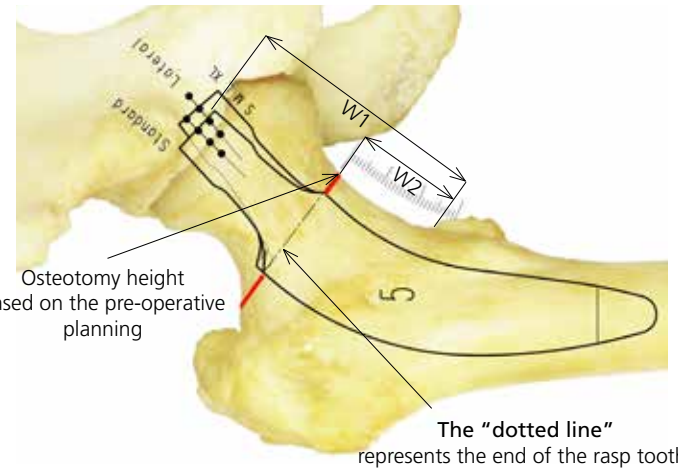
OSTEOTOMY OF THE FEMORAL NECK

The osteotomy is performed in slight external rotation and, if necessary, in slight hyperextension and can be performed

1 in situ or

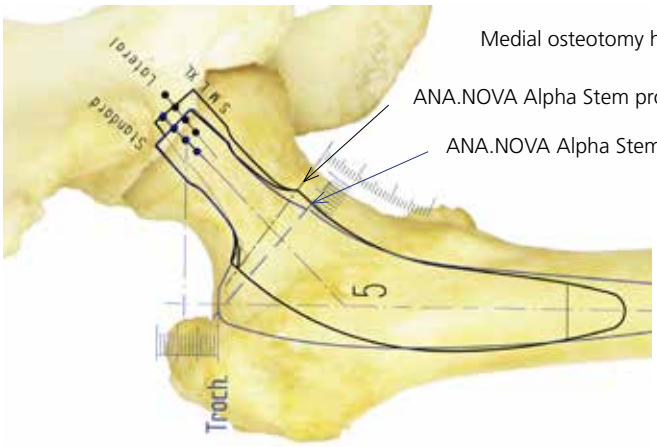
2 in situ with a disc removal

PLEASE NOTE **The exact femoral neck resection is determined during pre-operative planning and depends on the size of the femoral neck and its varus or valgus position.**



Osteotomy height based on the pre-operative planning

The "dotted line" represents the end of the rasp toothing on the X-ray template

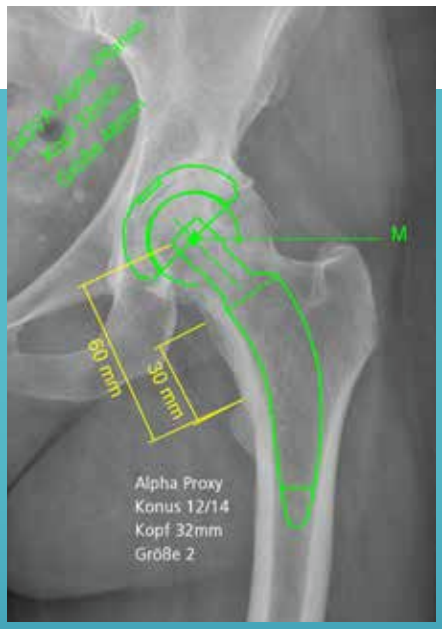


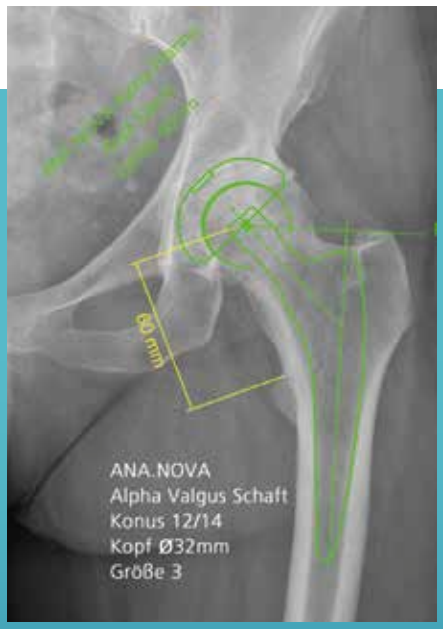
Medial osteotomy height

ANA.NOVA Alpha Stem proxy

ANA.NOVA Alpha Stem

If it becomes apparent intra-operatively that there is a contraindication, the ANA.NOVA Alpha Stem can be used as an alternative. In addition to the emphasised metaphyseal support, this universal stem also has a diaphyseal support (see surgical technique for ANA.NOVA Alpha Stem, Lit. no. 860104).



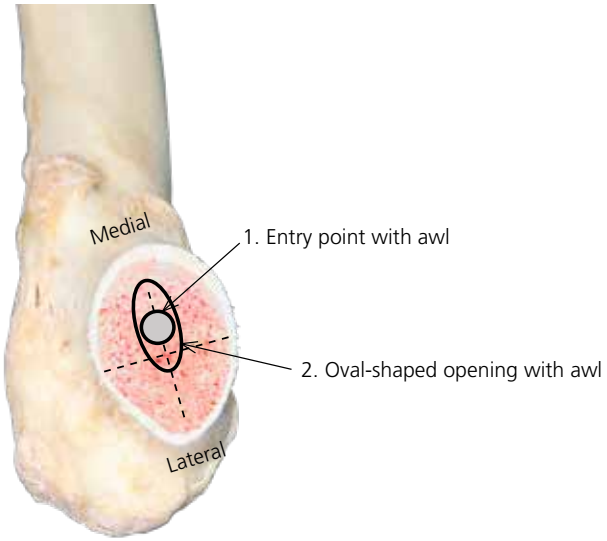


Opening the medullary cavity

1. OPENING AWL

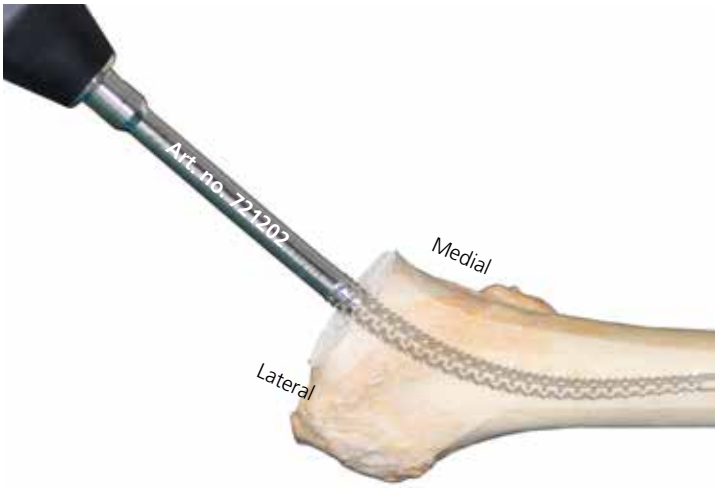
The medullary cavity is opened with a curved opening awl (art. no.721202) at the femoral neck osteotomy centrally, with a slight tendency towards the medial side.

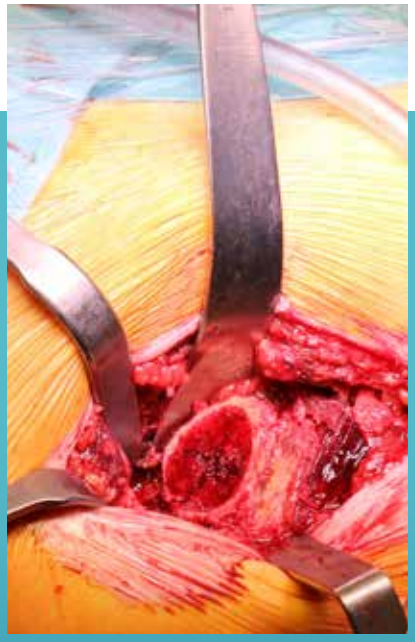
ATTENTION **Never open laterally! It is crucial that the implant rests on the medial cortical bone (Adams' arch). As a result, the entry point is slightly medial instead of lateral.**



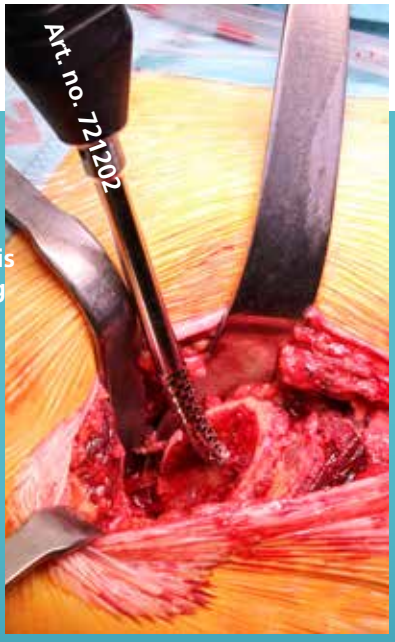
2. OVAL-SHAPED OPENING WITH THE OPENING AWL FOR CORRECT ALIGNMENT

Correct alignment is achieved with the complete insertion of the rasp through the natural shape of the femur and the femoral neck, which avoids a possible incorrect position of the subsequently placed stem.





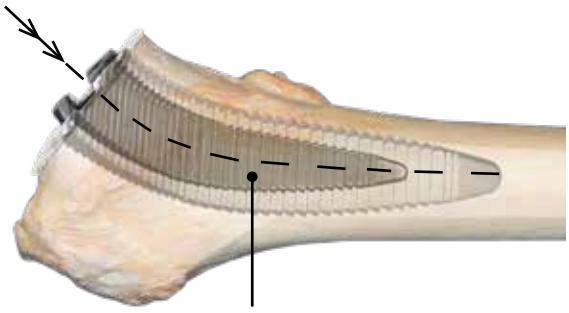
The anatomical antetorsion of the stem is simultaneously achieved by maintaining the femoral and femoral neck axis direction.



Rasping the stem bed

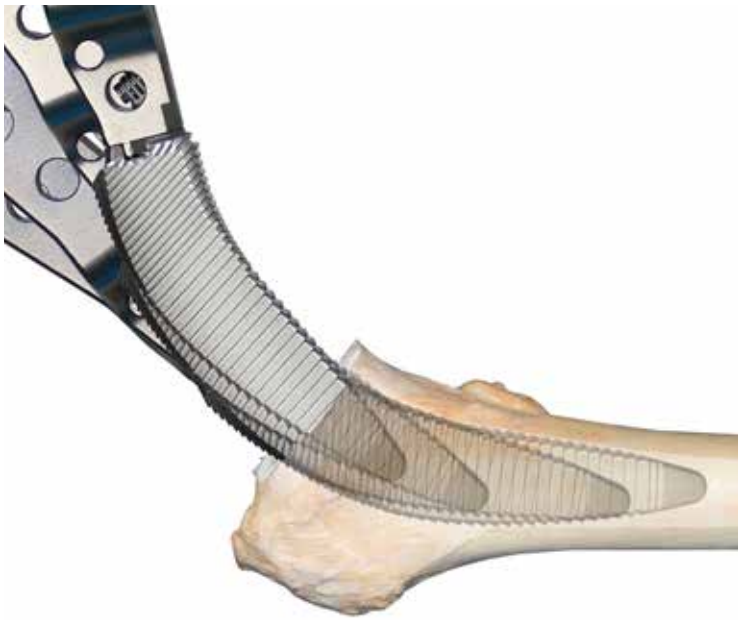
The metaphyseal medullary cavity is gradually rasped open by hand. Start with the smallest rasp.

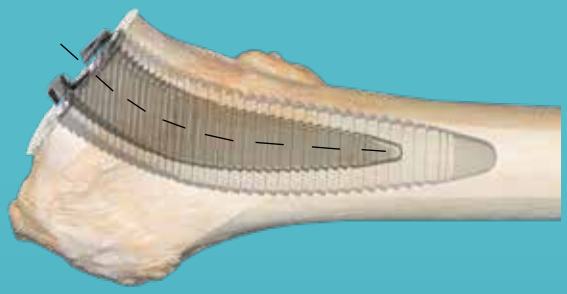
The selected adapter is placed on the rasp. The adapter with integrated double offset is used as standard. It is particularly suitable for anterior and antero-lateral approach.



Rasp size 0

It is essential that the rasp is also inserted in a **curved shape** using the curved rasp adapter (art. no.721203 and art. no. 721205). Rasping is continued with an optimal cortical fit up to the appropriate size.

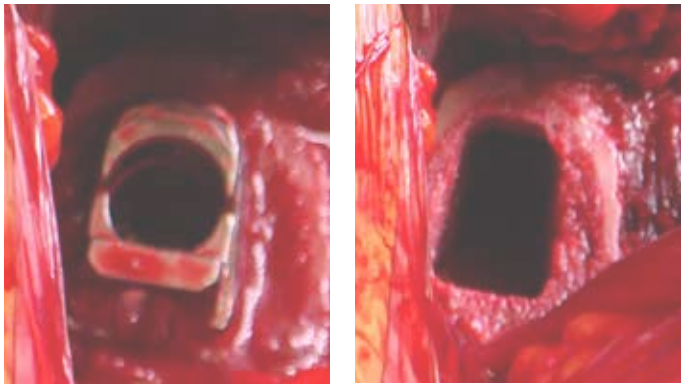


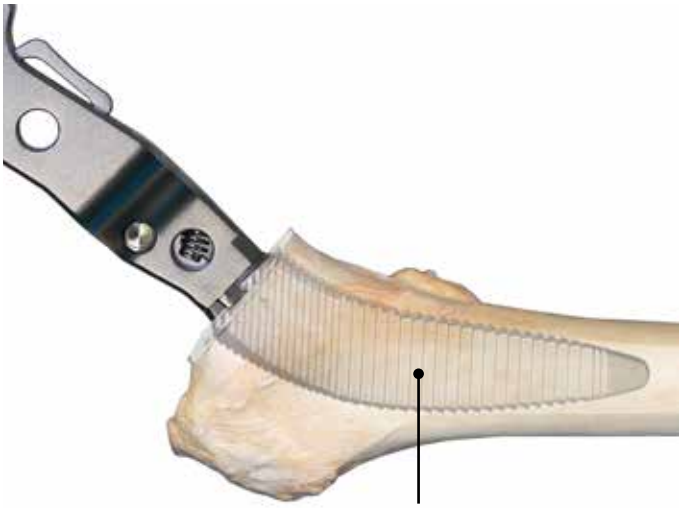


PLEASE NOTE

Each rasp size may only be inserted up to the planned position (resection plane). Penetrating too deeply would result in cancellous bone being removed from the femur, which can no longer be filled by the implant.

The design of the ANA.NOVA Alpha Stem proxy is such that all sizes can be implanted within the closed femoral neck ring.
It is therefore important to ensure that the rasping is carried out in a slightly medial position within the neck ring without breaking it.





Last rasp size with proximal cortical triple anchoring

The rasp sizes are then increased until a snug cortical fit is achieved. The largest possible rasp should be accommodated in the femur.

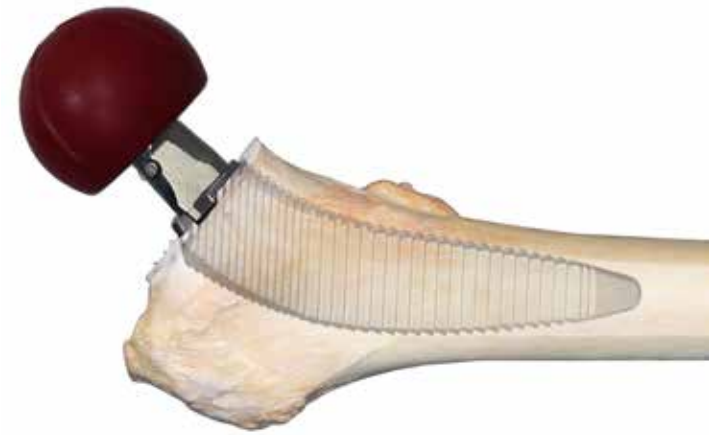
PLEASE NOTE

If the preoperatively planned size differs from the final rasped size, we recommend checking the correct axial position of the rasp using the image converter.

Manipulation

The standard manipulating neck (art. no. 721201) or the lateral manipulating neck (art. no. 721207) and the manipulating head are placed on the last rasp.

After reduction, an initial manipulation is performed and the achieved leg length, offset and dislocation tendency of the artificial hip joint are assessed.



Lateral, art. no. 721207
Black locking lever

Standard, art. no. 721201
Silver locking lever

PLEASE NOTE

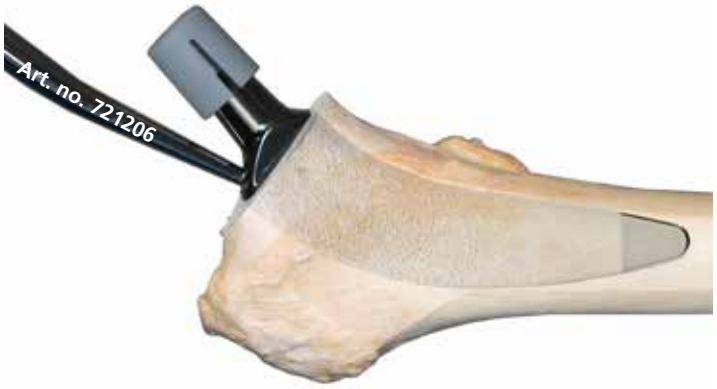
The locking levers are colour-coded to avoid confusion between the manipulating necks.

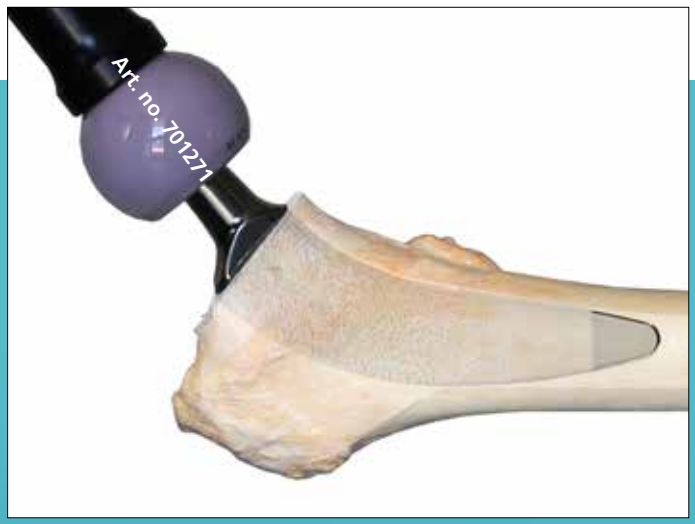
Setting the ANA.NOVA Alpha Stem proxy

Once the rasp bed has been prepared, the final stem size of the ANA.NOVA Alpha Stem proxy is selected according to the last rasp size used and inserted into the rasp bed by hand as far as possible.

You must ensure that the stem is inserted into the rasp bed without tension until a few mm before it is optimally seated. If the stem cannot be placed in the original bed of the rasp, check the bed to avoid possible misplacement.

The implant is driven in and fixed with light, controlled blows using a stem impactor (art. no. 721206).





Optionally, a further trial reduction can now be performed to test the joint tension and mobility with the manipulating ball heads.

The stem cone is then carefully cleaned by hand to remove any blood and tissue residue, the definitive ball head is attached with a slight twist and fixed in place with the ball head impactor (art. no. 701271) using light hammer blows.

Implant damage

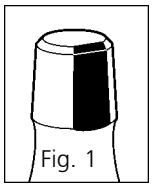
PLEASE NOTE **Care must be taken to ensure that there is no direct contact between the implant and the surgical instruments or electrocautery. Any contact can change the material and cause mechanical or thermal damage, which increases the risk of the prosthesis breaking.**

Due to these risks, a damaged prosthesis must be removed and replaced with a new one!

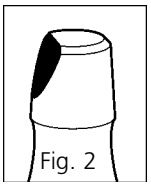
Ball head replacement

After removing the ball head that needs replacing, check the stem cone for nicks and scratches that may have been caused by striking it. If there are light pressure marks and scratches on the cone, the ball head system option can be used. If the cone is severely damaged (see Fig. 1 - 3), the ball head option must not be attached, **which is why the stem must be explanted.**

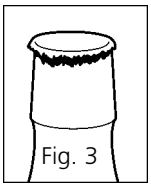
Test heads must be used to determine the collar length and to check the soft tissue balance and the range of movement.



Bevelled cone

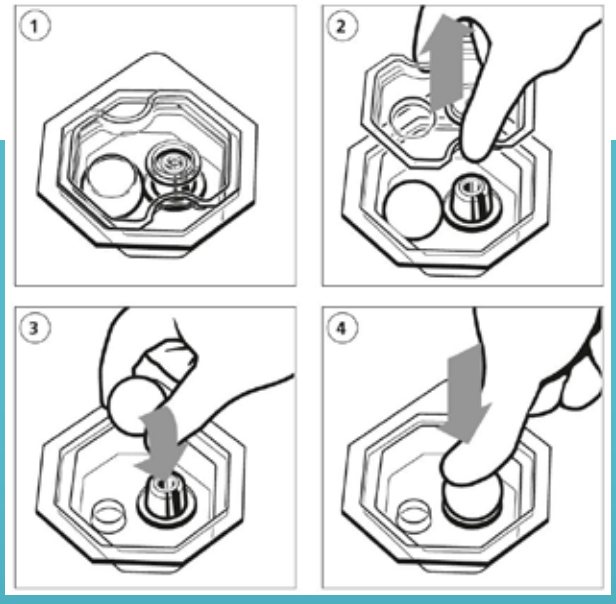


Cone with wide flattening



Squashed cone

Assembly and implantation



Assemble the ball head option with the titanium sleeve (see Figures 1 - 4).

Then carefully remove any blood and tissue residues from the stem cone. Place the ball head option onto the stem cone by hand using a twisting motion and apply pressure until it locks into place.

Fix using the ball head impactor art. no. 70127 to hammer lightly.

PLEASE NOTE

To avoid damaging the ball head and the neck of the stem, the plastic ball head impactor art. no. 701027 must be used!

Explantation

An extractor (art. no. 721204) with slide hammer coupling is available for removing prostheses.

Positioning of the extractor

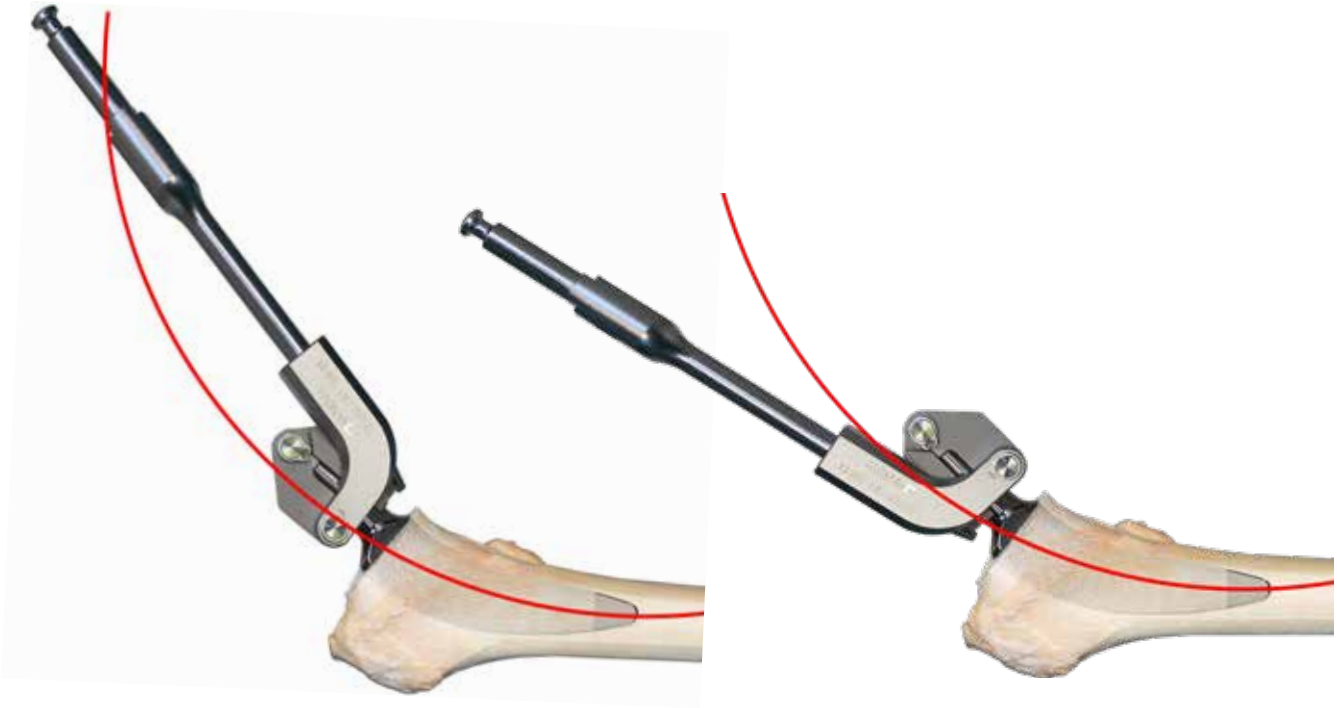
Depending on how the extractor is positioned on the stem cone, the stem can be deflected in two different tensile directions.

VARIANT 1

The deflection occurs medially via the Adams' arch.

VARIANT 2

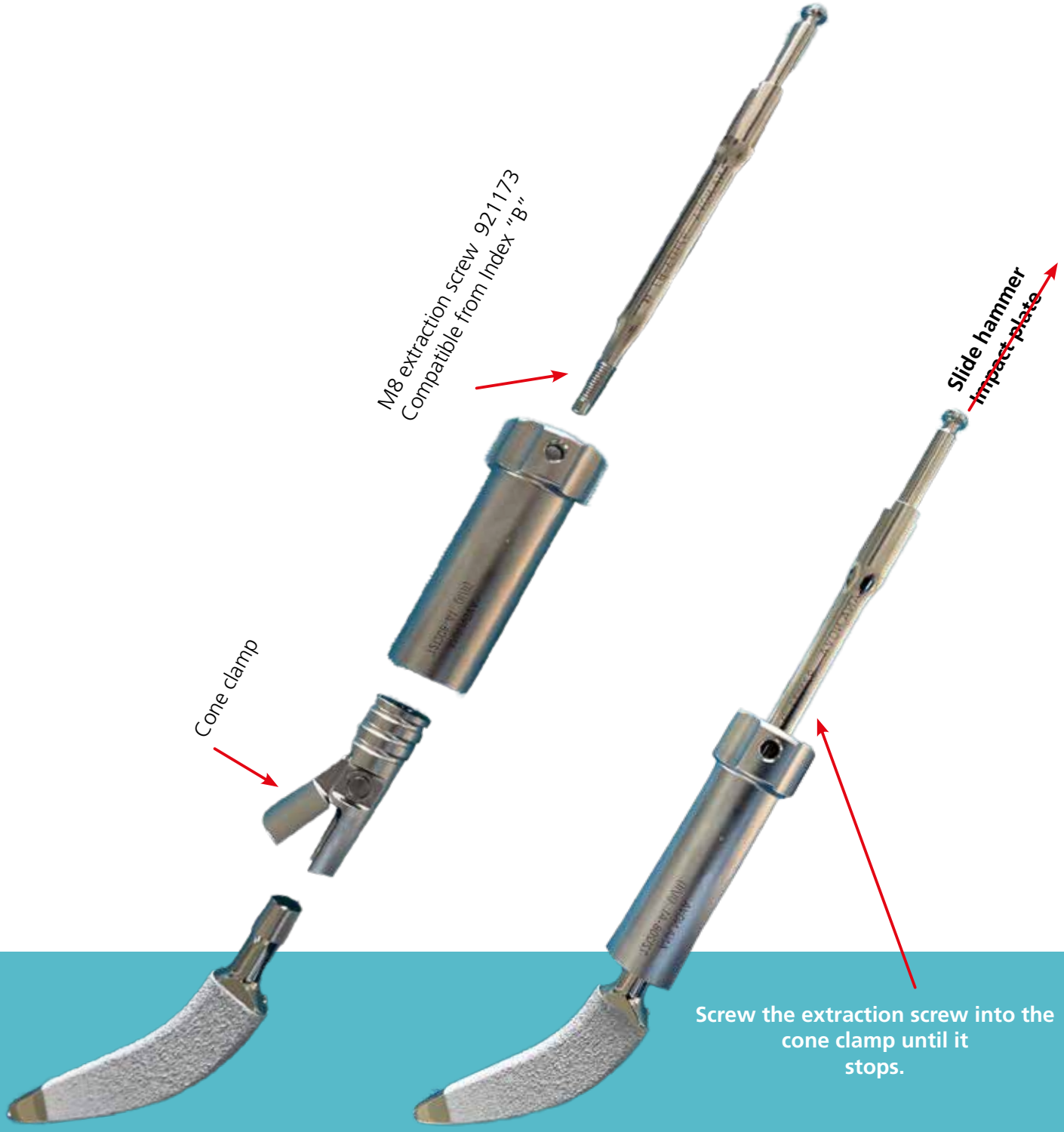
The deflection is in the direction of the greater trochanter.



PLEASE NOTE

The jaws of the extractor are made of plastic so as not to damage the stem cone unnecessarily. This material is not suitable for the explantation of very tight-fitting stems. Alternatively, a metal extraction adapter can be used here.

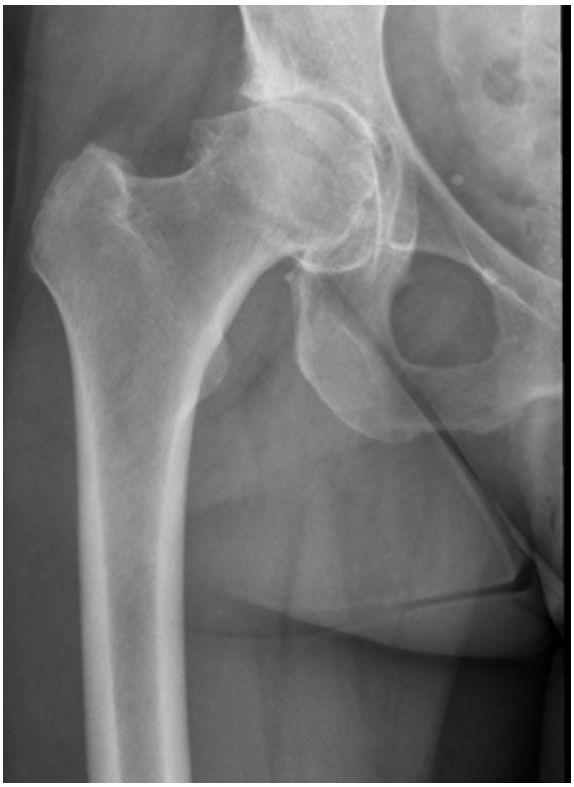
Short-stem extractor for 12/14 cone



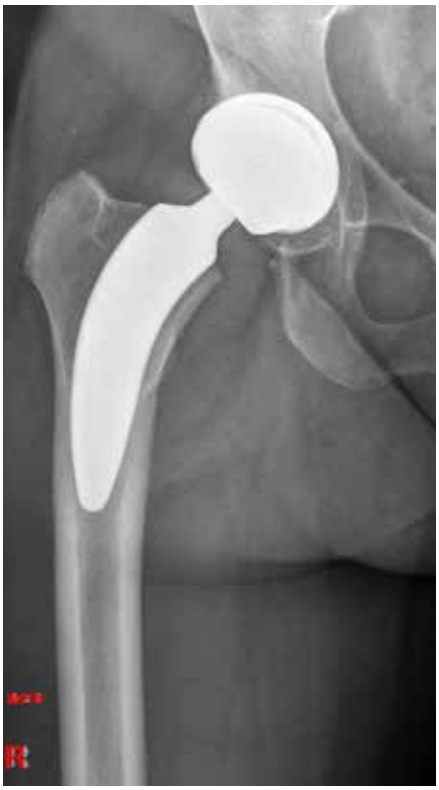
Art. no.	Description
721208	Short-stem extractor metal proxy
721210	Short-stem extractor metal "universal"

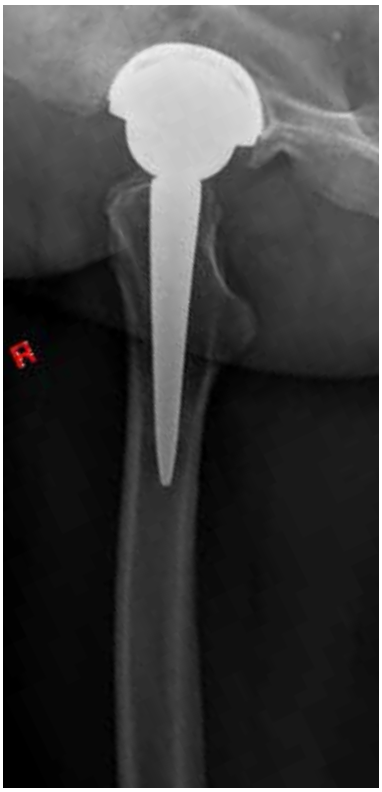
CASE STUDY 1

Pre-operative



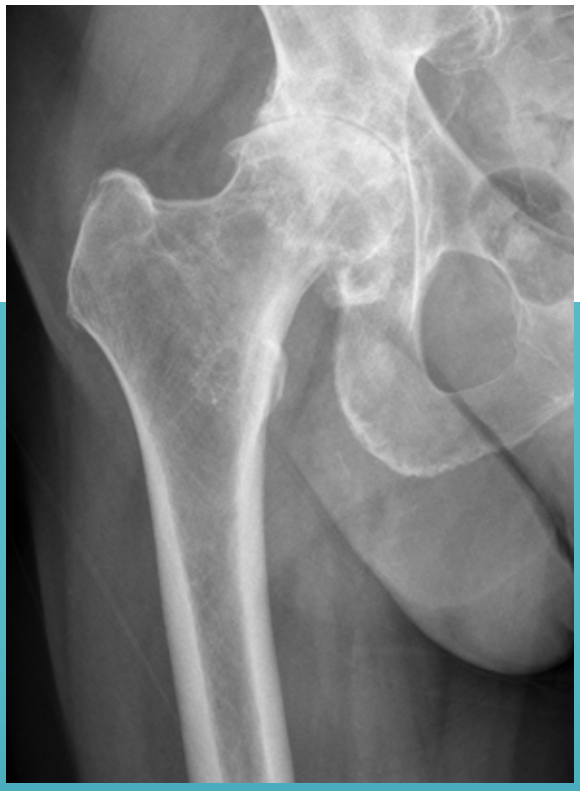
Post-operative X-ray images



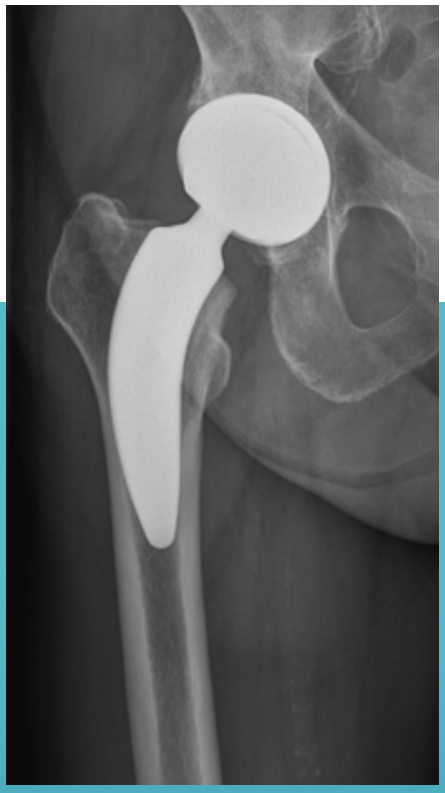


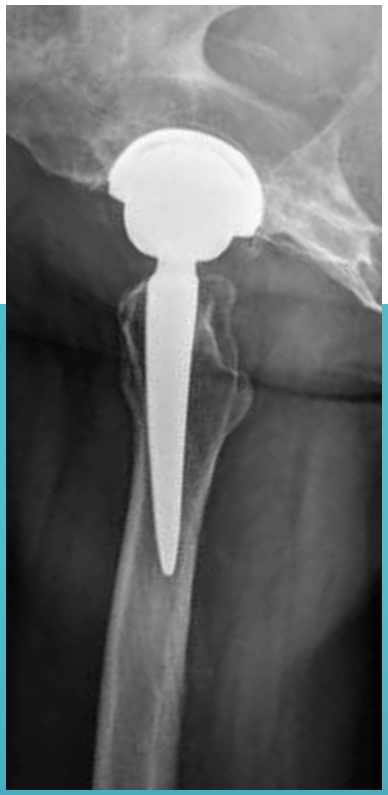
CASE STUDY 2

Pre-operative



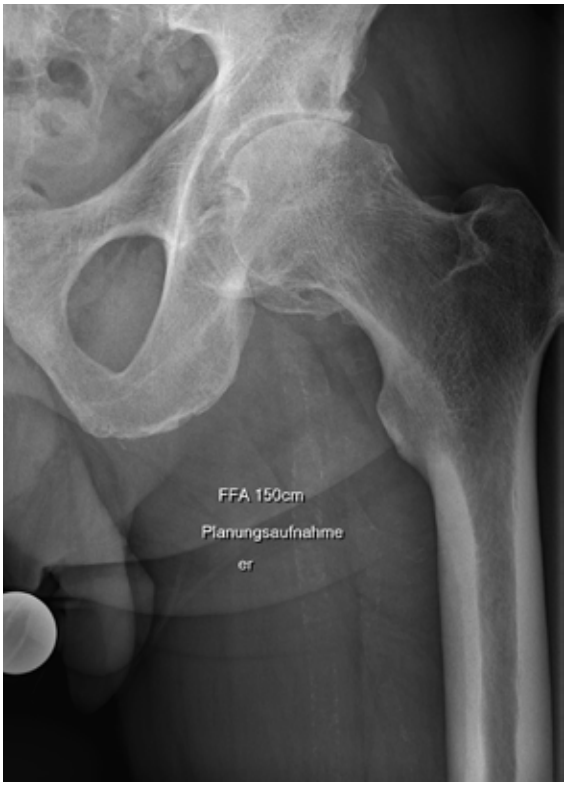
Post-operative X-ray images



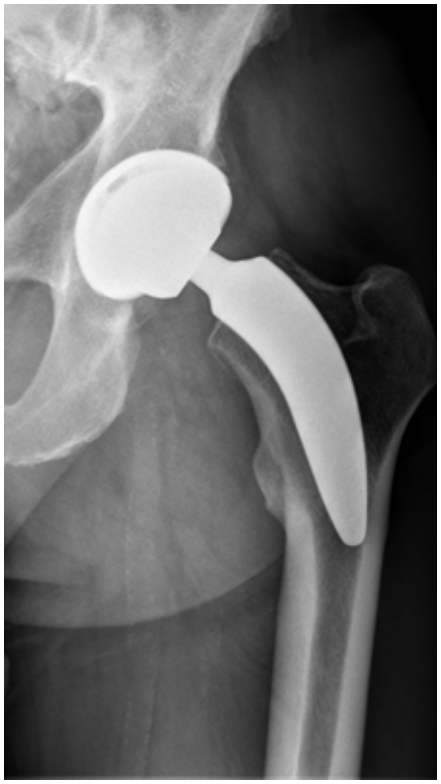


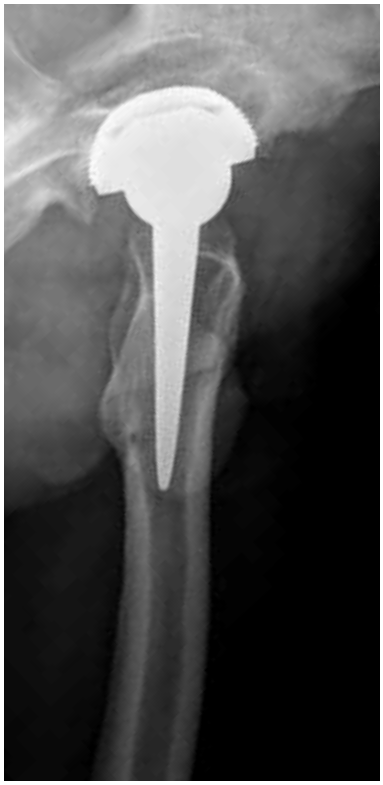
CASE STUDY 4

Pre-operative



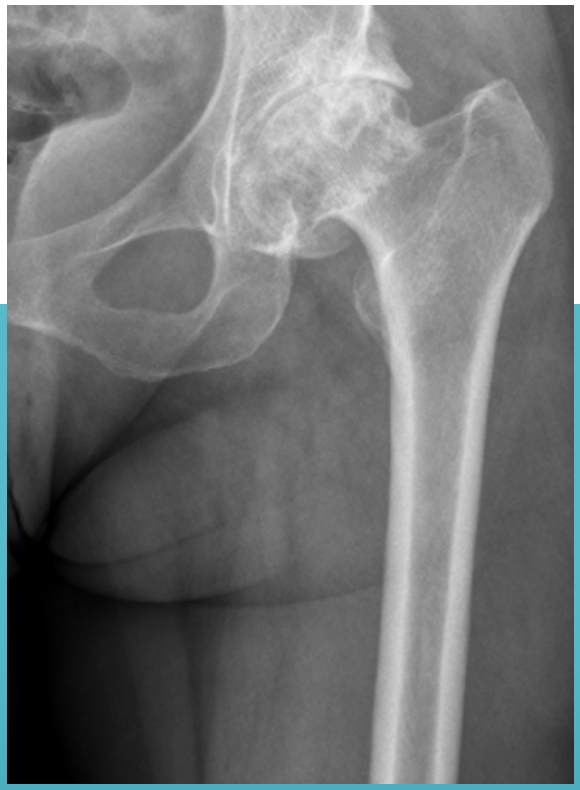
Post-operative X-ray images



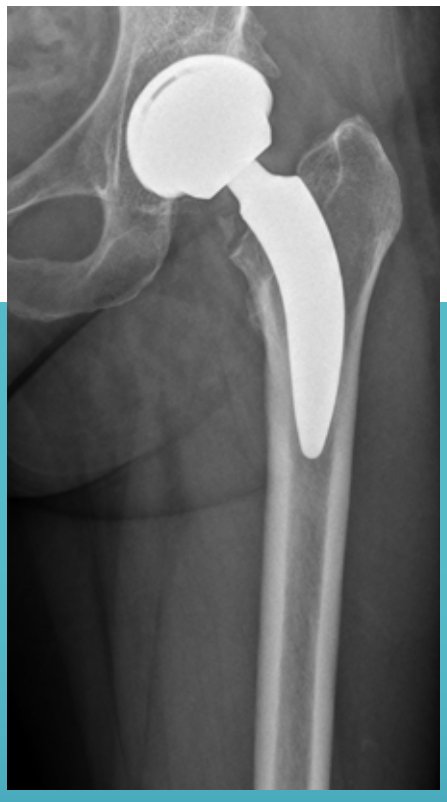


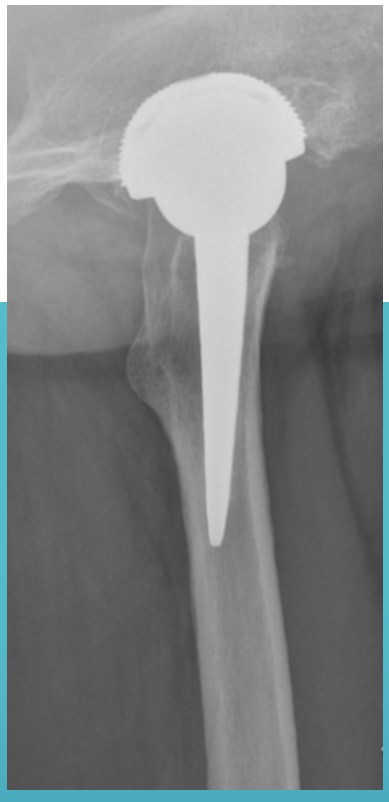
CASE STUDY 3

Pre-operative



Post-operative X-ray images





ANA.NOVA Alpha Stem proxy

Art. no.	Description	Size
72010	ANA.NOVA Alpha Stem proxy	0
72021	ANA.NOVA Alpha Stem proxy	1
72022	ANA.NOVA Alpha Stem proxy	2
72023	ANA.NOVA Alpha Stem proxy	3
72024	ANA.NOVA Alpha Stem proxy	4
72025	ANA.NOVA Alpha Stem proxy	5
72026	ANA.NOVA Alpha Stem proxy	6
72027	ANA.NOVA Alpha Stem proxy	7
72028	ANA.NOVA Alpha Stem proxy	8
72029	ANA.NOVA Alpha Stem proxy	9
72030	ANA.NOVA Alpha Stem proxy	10
72031	ANA.NOVA Alpha Stem proxy	11

Art. no.	Description	Size
72510	ANA.NOVA Alpha Stem proxy lateral	0
72521	ANA.NOVA Alpha Stem proxy lateral	1
72522	ANA.NOVA Alpha Stem proxy lateral	2
72523	ANA.NOVA Alpha Stem proxy lateral	3
72524	ANA.NOVA Alpha Stem proxy lateral	4
72525	ANA.NOVA Alpha Stem proxy lateral	5
72526	ANA.NOVA Alpha Stem proxy lateral	6
72527	ANA.NOVA Alpha Stem proxy lateral	7
72528	ANA.NOVA Alpha Stem proxy lateral	8
72529	ANA.NOVA Alpha Stem proxy lateral	9
72530	ANA.NOVA Alpha Stem proxy lateral	10
72531	ANA.NOVA Alpha Stem proxy lateral	11

Implant material: **Ti6Al4V according to ISO 5832-3**

Surface: Polished prosthesis neck and polished prosthesis tip, **blasted aluminium oxide, titanium plasma coating, full-surface bioactive calcium phosphate coating BONIT, cone 12/14**

ANA.NOVA ceramic ball head

Neck length	Ø 28	Ø 32	Ø 36	Ø 40
S	90601	90611	90621	90631
M	90602	90612	90622	90632
L	90603	90613	90623	90633
XL	-	90614	90624	90634

Implant material:
BIOLOX delta according to ISO 6474
Cone 12/14

Only available on request

Ceramic OPTION ball head

Neck length	Ø 28 mm	Ø 32 mm	Ø 36 mm	Ø 40 mm
S	59001	59011	59021	59031
M	59002	59012	59022	59032
L	59003	59013	59023	59033
XL	59004	59014	59024	59034

Implant material:
Ball head: **BIOLOX delta according to ISO 6474**
Socket: **TiAL6V4 according to ISO 5832-3**
Cone 12/14

ANA.NOVA ALPHA STEM PROXY

No.	Art. no.	Description
1	721010	Alpha Stem proxy mesh
2	721110	Alpha Stem proxy stem rasp 0
3	721111	Alpha Stem proxy stem rasp 1
4	721112	Alpha Stem proxy stem rasp 2
5	721113	Alpha Stem proxy stem rasp 3
6	721114	Alpha Stem proxy stem rasp 4
7	721115	Alpha stem proxy stem rasp 5
8	721116	Alpha Stem proxy stem rasp 6
9	721117	Alpha Stem proxy stem rasp 7
10	721118	Alpha Stem proxy stem rasp 8
11	721119	Alpha Stem proxy stem rasp 9
12	721120	Alpha stem proxy stem rasp 10
13	721121	Alpha stem proxy stem rasp 11
14	721201	Manipulating neck proxy standard
15	721207	Manipulating neck proxy lateral
16	721202	Opening awl proxy
17	721203	DO Rasp adapter proxy left
18	721205	DO Rasp adapter proxy right
19	721206	Stem impactor proxy
20	1099970	Hammer 700g
21	721204	Stem extractor proxy I/II
22	721204	Stem extractor proxy I/II
23	701271	Ball head impactor
24	921309	Crossbar for impact plate
25	921311	Impact plate 140
M1	2160000	Mesh insert for manipulation heads
M2	2160001	Manipulating head 28S
M3	2160002	Manipulating head 28M
M4	2160003	Manipulating head 28L

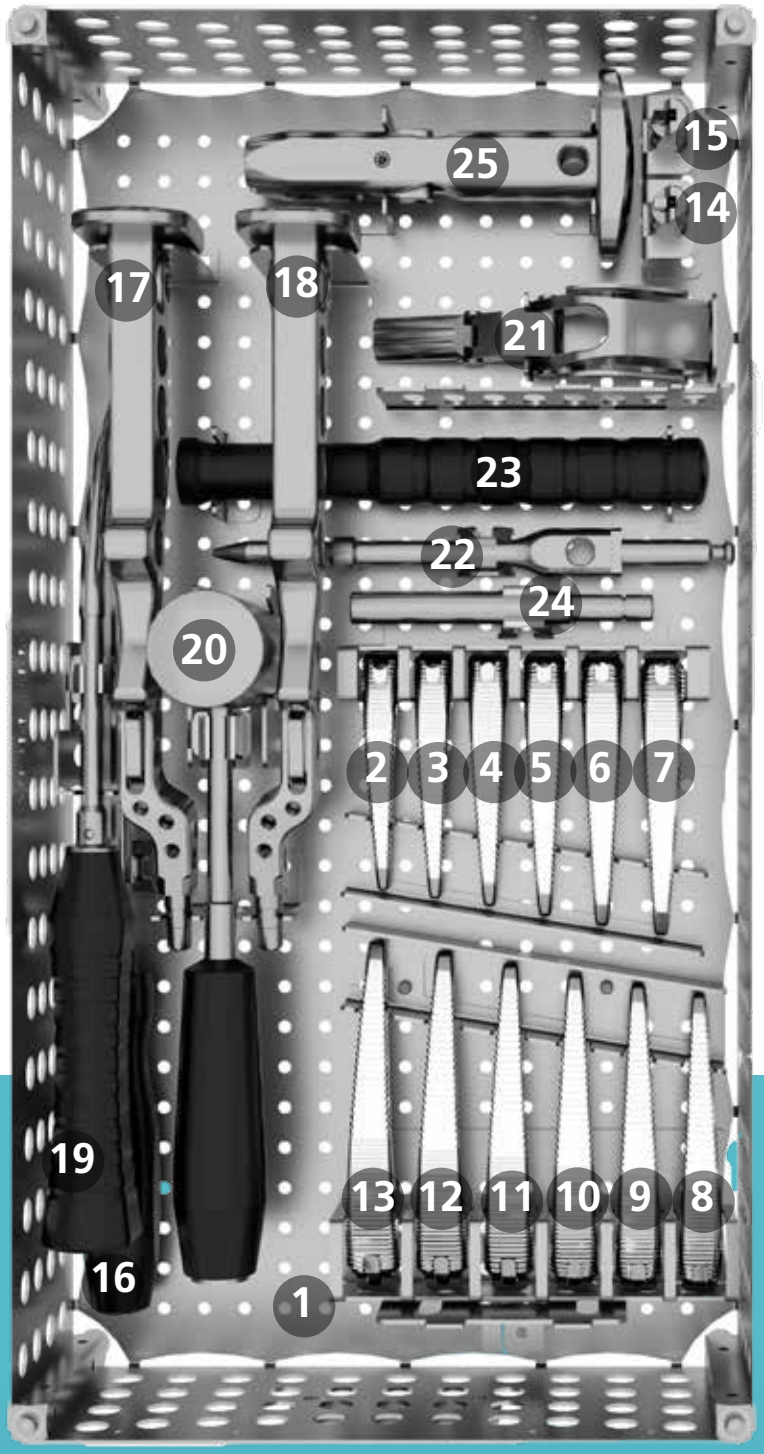
No.	Art. no.	Description
M5	2160011	Manipulating head 32S
M6	2160012	Manipulating head 32M
M7	2160013	Manipulating head 32L
M8	2160014	Manipulating head 32XL
M9	2160016	Manipulating head 36S
M10	2160017	Manipulating head 36M
M11	2160018	Manipulating head 36L
M12	2160019	Manipulating head 36XL
M13	2160021	Manipulating head 40S
M14	2160022	Manipulating head 40M
M15	2160023	Manipulating head 40L
M16	2160024	Manipulating head 40XL
	721208	Short-stem extractor metal proxy
	721210	Short-stem extractor metal “universal”
	921173	Extraction screw M8 (from Index B)
	999019	Trochanter cone lineal

Standard

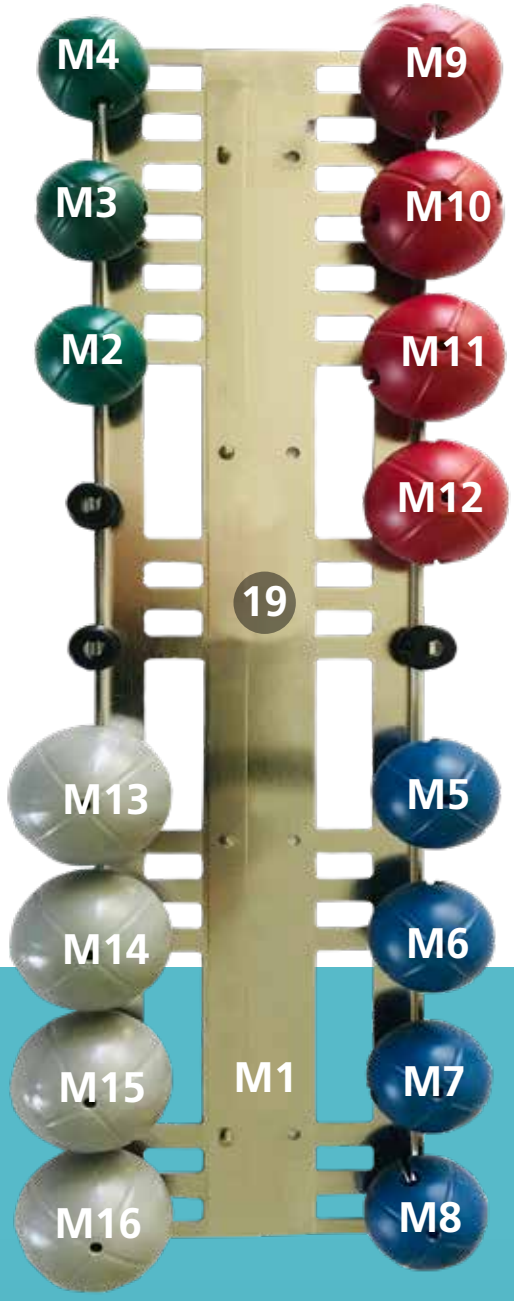
Optional

Weight with full equipment: 9.60 kg

ANA.NOVA ALPHA STEM PROXY



Mesh insert for manipulation heads



Post-operative aftercare

Aftercare depends on the result of the operation. In principle, mobilisation can be started early after implantation. The implementation and type of mobilisation, such as partial weight-bearing, full weight-bearing, crutches, three-point gait, four-point gait, etc., depend on the surgeon's recommendation. The bone quality and the patient's condition are always taken into account. Physiotherapy is recommended during the hospital stay.

MRT / CT examinations

MRI / CT examinations can cause undesirable effects that are harmful to the patient. Possible effects include artifacts, heating of the implant, induction of electrical currents, loosening of the implant. Before use, study the instructions provided by the appliance manufacturer. In case of doubt, comparative implants should be checked for suitability in the respective MRI / CT device as part of an individual risk assessment. The patient must be informed of the risks.

General information

On request, ImplanTec GmbH can test and assess compatibility of third-party products with its products. Further information on implant materials and the electronic instructions for use (eIFU) can be found at www.implan-tec.at.
If required, the instructions for use can also be requested in paper form free of charge.

Storage of sterile implants

Implants should always be stored in their unopened packaging. The packaging of the implants is designed so that they can be stored at normal room temperature / relative humidity (corresponding to the usual "storage and working climate" in our latitudes, i.e. between approx. +15°C and +35°C depending on the time of year with correspondingly normal relative humidity) without risking damage to the packaging, sterility, product, etc. Sterile implants must not be exposed to sunlight without protection (i.e. without protection from light from the packaging).

Sterilisation

IMPLANTS

All implants described in the surgical technique are supplied sterile by the manufacturer.
They must not be resterilised.

INSTRUMENTS

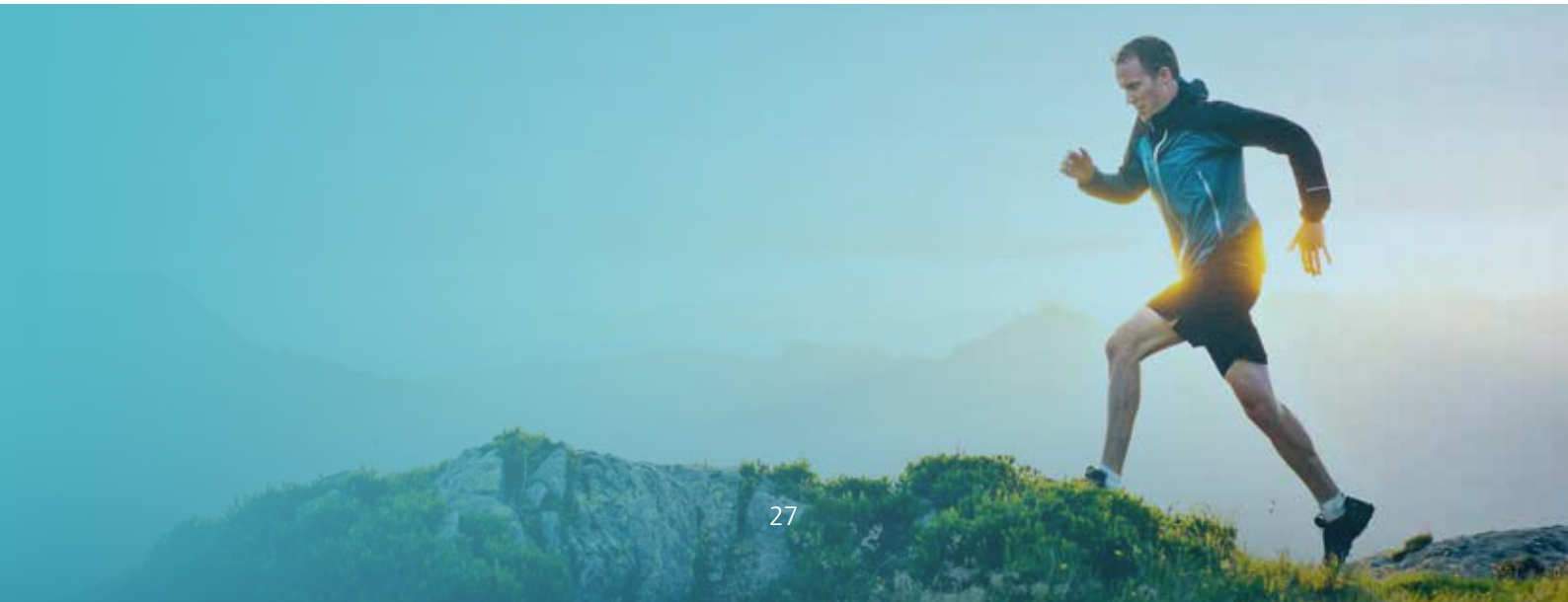
The system elements and instruments are not sterile when delivered. Before use, they must be cleaned, disinfected and sterilised according to a validated procedure. The cleaning instructions (ref. no. 860501) contain validated instructions for preparing a medical device for reuse.

The person who carries out this process is responsible for ensuring that the desired results are achieved by means of the available equipment, materials and personnel in the handling facility. This usually requires validation and routine monitoring of the process.

Instrument manufacturers and distributors accept no responsibility for the sterilisation of products by the purchaser.

CE marking

Marking CE 0483 only for implants of risk class III and surgical instruments of risk class IIa and Ir for products manufactured by ImplanTec GmbH.



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for the individual needs of patients.