Surgical Technique
The NESimplavit® Elbow System is developed and manufactured in conjunction with the orthopedic surgeons Dr. Jan August Pahle and Dr. Jens Teigland.

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**Nota Bene:** The described surgical technique is the suggested treatment for the uncomplicated procedure. In the final analysis the preferred treatment is that which addresses the needs of the individual patient.
INTRODUCTION

This Elbow System represents an non-constrained joint replacement of the ulno-humeral joint of the elbow. Only the soft tissues are restricting the range of motion and the intact ligaments and tendons are stabilizing the joint. Based on the medical and surgical knowledge of the authors it is an improvement of former clinical proven designs. A ligament and soft tissue preserving surgical technique is combined with a minimal bone resection.

The humeral implants are available in 4 different sizes and can be combined independently with the 3 ulnar sizes. Ulnar and humeral components are made of cast CoCrMo alloy. The bobbin is made from UHMWPE and articulates against the ceramic coated axle. This axle is made from TiAl6V4 which is coated with TiN to reduce the polyethylene wear.

This system is for cemented use only. Suture holes in the side flanks of the humeral components allow the refixation of bone fragments. The axle of the preassembled humeral components is secured by a torque wrench.
DESIGN FEATURES

SURGICAL APPROACH

Position the patient in the lateral decubitus position with the affected arm free (fig. 1). Open the skin through a dorsal midline incision from 8-10 cm above the olecranon to 6-8 cm distal to the olecranon (fig. 2). Split the triceps fascia and tendon in the direction of the fibres app. 2-4 mm lateral to the lateral corner of the olecranon.

Fig. 1: Positioning of the patient

Fig. 2: The skin incision
Use a blunt splitting technique to split the triceps between the long and the lateral heads. By pushing the deep head laterally you reach the distal humerus and the capsule (fig. 3).

The incision is carried distally along the ulna through the fascia and the underlaying anconeus muscle along the insertion on the lateral side of ulna, down to the annular ligament of the radius (fig. 4).

Fig. 3 and 4: The triceps muscle split between the long and the lateral head

The lateral and deep heads of the triceps should be kept in continuity with the lateral part of the triceps tendon and fascia. The long head of the triceps is still fully attached to the olecranon.

Preserve the collateral ligaments carefully during the opening of the joint capsule. Perform always a thorough synovectomy and resect the radial head (app.12mm).

Remove all osteophytes to mobilise the joint, especially along the medial side of the olecranon and the semilunar notch to the coronoid process. The medial rim of the coronoid is preserved to protect the insertion of the anterior bundle of the medial collateral ligament.
HUMERAL PREPARATION

A partial resection of the olecranon improves the access to the medial side of the joint. Avoid injury to the ulnar nerve. Although the nerve is not routinely transposed it can be under excessive tension or pressure. Resection of the radial head is commonly considered to release the joint (fig. 5a and 5b).

Fig. 5a: Exposed joint  Fig. 5b: Rotation axis of the trochlea

Place a pin on the dorsal flat of the humerus 30-40 mm above the inter-epicondylar line, it corresponds well with the normal axis of the trochlea (fig.6). Resect the central part of the trochlea in the axis of the humeral shaft. Use an nibbler or an awl to open the medullary cavity of the humerus to introduce the small humeral broach. Ensure the correct rotation of the broach. If the trochlea is severly deformed it may be difficult to examine the trochlea correctly.

Use the slotted hammer to drive the broach carefully with small strokes in and out. If the reaming appears easy, the large broach should be used in the same way to enlarge the bone preparation. Insert the broach until the marking reaches the joint line (fig. 6).

Fig. 6: Humeral broach with marking
OPTION A

The following steps are describing the humeral box preparation while using the template and the special NES sawblade or an other thin and small type to cut out the humeral bone. This technique is recommended when the distal bone structure is too weak and the humeral resection guide could not be aligned and fixed securely to the bone (OPTION B using the humeral resection guide).

Fig. 7: Resection of the humeral trochlea

Prepare the grooves for the side flanks with a small burr. Prevent a too tight fitting of the humeral component because this might lead to stress fractures of the epicondylar ridges. The broach can be used to prepare the grooves (fig. 8).

Fig. 8: Preparing the grooves
OPTION B

The following technique describes the use of the humeral resection guide to cut out the distal humeral bone.

Leave the broach of the correct size in the medullary cavity of the humerus. Slide the humeral resection guide over the broach (fig. 9a).

Make sure that the guide is aligned parallel to the intercondylar line of the distal humerus. Use the screw to lower the resection plate until it rests onto the bone surface of the posterior humeral bone (fig. 9b).

Insert two of the NES drills into the resection guide to fix it in the correct position. The drills have a stop to prevent damages or stress fractures of the epicondylar ridges (fig. 10a). Leave the drills in position to stabilise the guide (fig. 10b).
When the guide is fixed securely to the bone the distal preparation can follow. Use the special NES sawblade or an other thin and small type to resect over the rim of the cutting plate and cut out the box (fig. 11a and 11b).

Fig. 11a: resection guide side view  
Fig. 11b: Bone resection

Prevent damage of the broach and/ or the sawblade while finalizing the bone cut in the proximal part (fig. 12a). If necessary remove the drills, the resection guide and the broach first and finish the bone resection in the proximal part (fig.12b)

Fig. 12a: Resected of the distal bone  
Fig. 12b: Finished bone resection
The preparation of the grooves for the flanks of the prosthesis is done by the remaining drill holes (fig. 13). Insert the humeral trial by using the humeral impactor (fig. 14).

The humeral component should be inserted until it stops against the remaining trochlea (fig. 15a).
Prevent a too tight fitting of the humeral component it might lead to stress fractures of the epicondylar ridges. If the joint line is not restored correctly (fig. 15b) please use humeral trials with 5 or 10mm.
Remove the trial component before the begin of the ulna preparation.
ULNAR PREPARATION

Define the medullary cavity of the ulna and open it with an awl just ventral to the angle between the bone cuts. Perform the ulna resection with two saw-cuts. Removing little more than the articular surface.

Resect first perpendicular to the plane of the ridge of the ulnar notch, parallel to the axis of the ulna, and then at rectangular to this into the tip of the coronoid process.

Fig. 16: Opening of the medullary cavity Fig. 17: L-resection of the ulna

Use the smallest broach first. Avoid external malrotation by respecting the plane of the semilunar ridge and the dorsal flat of the proximal ulna. Malrotation can cause rupture of the medial collateral ligament if the elbow is extended. Use the broach carefully with the sliding hammer back and forth.

The asymmetrical tip of the broach should be directed laterally (fig. 18a). Make sure that the marking RAD is facing to the radius. Insert the broach until the depth mark (fig. 18b) reaches the most edge of the bone.

Fig. 18a and 18b: Ulna broaching and broach marking
TRIALING REGIME

Insert the ulnar trial component in the correct rotation. Mark the position of the anterior bowed flange and make a groove with a burr.

Usually the large components will fit to males and females. Smaller sizes are only used if the medullary cavities are so narrow that the large broaches cannot be introduced without too much resistance. This appears in juvenile RA.

Do a trial reduction before cementing the prosthetic components and check the tension of the collateral ligaments. The humeral trial component, with the metal bobbin is first seated in the humerus, and then the ulnar trial is introduced into the ulna. Be careful because every reduction requires a stretching of the ligaments of app. 7-9 mm for the anterior horn of the ulnar component to pass over the bobbin.

Fig. 19 and 20: The trial reduction

If ligaments are too tight please check the following:

1) Insert the ulnar component deeper into the bone.
2) Seat the humeral component deeper.
3) Correct any malrotation of the components
4) Remove Osteophytes perhaps with partial sacrifice of the medial collateral ligaments.

Save as much bone as on the sides of the olecranon, not to jeopardise the triceps insertion or to risk a fracture.

If the collateral ligaments seem too slack, the prosthesis may be unstable. To reach adequate ligament tension it might be necessary to use a humeral component with an offset of +5 or +10 mm.
CEMENTING OF THE COMPONENTS

The components are fixed with bone cement, preferably in two stages: First the humeral component with the bobbin and then the ulnar component.

Ensure a good cement penetration into the medullary cavities and into the grooves for the flanks of the humeral component.

Remove all remaining bone cement.
Do the final reduction after hardening of the bone cement.

Fig. 21a and 21b: The final reduction

Fig. 22a and 22b: Implanted prosthesis
USE OF THE STABILISATION CLIP OR THE REVISION RING

In some cases in which a subluxation risk is high or the circumstances of the patients needs more intrinsic stability of the joint the systems allows to increase the strength of the humero-ulnar coupling.

The stabilisation clip will not increase the constrained of the coupling, only prevent subluxations. The revision ring will constrain and will take part in the articulation therefore it is TiN coated (ceramic coating). Please consider that the use of the revision ring will change the NES Elbow replacement from a “sloppy hinge” into a semi constrained hinge with increased forces transferred into the bones.

POSTOPERATIVE TREATMENT

Post-operatively the arm is elevated in an abducted position so that" the elbow is higher than the heart".

Guided active motion of the elbow joint may start an the first post-operative day as no important tendon has been divided. Active motion in full range may be expected within two weeks. It is emphasized the neighbouring joints, e. g. the wrist and the finger joints, should be trained actively from the first day.
SYSTEM OVERVIEW

IMPLANTS

humeral components
(preassembled with PE bobbin and axle)
8100-0010 small left
8100-0011 large left
8100-0012 large +5mm left
8100-0013 large +10mm left

8100-0020 small right
8100-0021 large right
8100-0022 large +5mm right
8100-0023 large +10mm right

ulnar components
8100-0110 mini left
8100-0111 standard left
8100-0112 large left

8100-0120 mini right
8100-0121 standard right
8100-0122 large right

8100-0212 NES stabilisation clip
8100-0213 NES revision ring

TRIAL COMPONENTS

humeral trial components
8100-1010 small left
8100-1011 large left
8100-1012 large +5mm left
8100-1013 large +10mm left

8100-1020 small right
8100-1021 large right
8100-1022 large +5mm right
8100-1023 large +10mm right

ulnar trial components
8100-1100 mini left
8100-1101 standard left
8100-1102 large left

8100-1120 mini right
8100-1121 standard right
8100-1122 large right
INSTRUMENTS

8100-2013   NES sterilisation tray 1

8100-2014   NES sterilisation tray 2

8100-2000   NES humeral broach sm
8100-2001   NES humeral broach lg

8100-2002   NES ulnar broach mini
8100-2003   NES ulnar broach std
8100-2004   NES ulnar broach large

8100-2005   NES humeral impactor/extractor

8100-2006   NES ulnar impactor/extractor

7512-0901   ic hammer

7512-0900   ic T-handle (2x)

8100-2015   NES humeral resection template

8100-2020   NES Sawblade

8100-2010   NES drill (2x)

8100-2008   NES humeral resection guide
Note
The NESimplavit® system is a successful therapy, freeing patients from pain and restricted mobility.

The system’s main objectives are pain reduction and the restoration of physiological functions. Suitable patients should be selected according to the following conditions:

1) Patients disposing of adequate bone quality and with a bone structure that is likely to be preserved.
2) Patients, whose anatomic features allow for an adequate implant size for the prospective loading and degree of activity.
3) Patients who are willing and able to follow their physician’s directions, especially with respect to the necessary total or partly stress reduction on the implant during the postoperative period.

Patients must be warned of the consequences of excessive weight-bearing, sport participation and any activity causing excessive strain or impingement on the implanted prosthesis.

Used materials
The NESimplavit® implants consist of a cast CoCrMo-alloy (ISO 5832/4) The PE-components contain UHMW-PE (ISO 5834/2). Most of the instruments are made of acid-resistant stainless steel.

Indications
Adequate patient selection as well as a profound surgical analysis of the case are the basis of the whole surgical procedure. Careful preoperative planning and a precise surgical technique are necessary to obtain optimal results. In order to minimize the danger of postoperative complications different factors must be considered, i.e. the anatomical stress situation, the soft tissue basis and the planned component alignment.

To restore the anatomical function of the skeleton it may be necessary to repair and/or support/stabilize a traumatised or otherwise affected bone segment, to fuse it with other fragments or replace it by a prosthesis.

The treatment of rheumatoid arthritis, osteoarthritis and similar diseases with the NESimplavit® system can either be performed as an initial or a follow-up surgery, each with its corresponding surgical technique.

The NESimplavit® system is mainly implanted in cases of RA disease.

Contraindications
The main contraindications are bacterial infections, soft tissue defects due to irradiation, expected bone growth as well as - under certain conditions - better alternatives as e.g. a resection arthrodesis for infants. Other contraindications include:

1) Anatomical conditions which do not allow for or will not maintain sufficient bony support of the implant or which do not allow for an adequate implant size.

    In general i.e.:

    a) Insufficient blood supply caused by preceding surgeries or vessels affected by alcohol abuse etc.,
    b) insufficient quantity and quality of bone material due to osteoporosis, adipositas etc.,
    c) infections or other causes leading to reduced stability of the implant fixation.

2) Any mental or neurological conditions affecting the patient’s will to follow restrictions in activity, especially during the post-operative healing process. These could be drug abuse, mental illness, senility and general neurological limitation. 3) Conditions leading to extreme stress on the implants, such as myopathies, multiple arthropathies etc.

Contraindications can be absolute or relative and must be carefully considered with respect to the whole patient status and the prognoses of possible alternative therapies such as e.g. a conservative treatment, an arthrodesis etc.

Possible adverse effects:
1) Device component loosening, distortion or fracture. Normally these effects are caused by one or several of the mentioned factors, listed above and below under contraindications and warnings.

2) Migration, subluxation and rotation of the implant, flexion contraction, reduced mobility, increased or decreased leg length, component loosening or bone wear and ligamentary laxity.

3) Fractures of the ulnar and humerus.

4) Acute postoperative wound infection, severe sepsis and/or low-grade synovitis.

5) Neuropathy

6) Cardiovascular disorders: wound-haematoma, thrombosis and embolism (e.g. venous thrombosis and pulmonary embolism)

7) Tissue reactions: phagocytal reactions, foreign body reactions and myositis ossificans. These reactions especially apply to male patients with hypotrophic arthrosis, preoperatively limited mobility and/or preceded myositis. The risk of a myositis ossificans is increased by preceding surgeries or acute infections.

Warning and Precautions
Implant loosening, bending, fissure and/or breakage and other complications can occur if the following instructions and warnings are not considered and followed.
IMPORTANT MEDICAL INFORMATION

Preoperative
1) In every surgery a sufficiently wide range of implant sizes must be present. The preoperatively chosen implant, as well as the next bigger and smaller sizes must be prepared. Before insertion, the implant must be carefully checked to make sure that there is no damage or modification and that the correct size has been selected.
2) The implants are to be handled with care at all times, in order to avoid damage of the prepared implant surface. Cutting, bending or scratching of the component surfaces can considerably reduce their stability and resistancy against fatigue and wear. Even not directly visible defects can cause stress conditions within the implant, which can - because of the dynamic stress within the body - possibly lead to implant failure. If the preoperative observation shows that the modularity of the system can not fit the patient the use of a customised implant is necessary.
3) Allergies and other reactions to implanted materials should be considered, tested (if indicated) and excluded preoperatively, even if very uncommon.
4) The introducing instruments must correspond to the implant and must therefore belong to the NESimplavit® system.
5) A description of the surgical technique is available from the manufacturer. In order to obtain best possible results the surgeon must be familiar with the recommended surgical techniques for this system and its proper use.

Intraoperative
1) Adequate and durable component support, obtained through cementation and/or bone material, as well as the correct selection of the component size are of vital importance.
2) During the process of cement hardening any repositioning of the implant components should be avoided.
3) After insertion of the stem, its plate must be flush against the resected bone. It is important to resect the bone plane, horizontal to the medullary cavity.
4) For the ulnar and humerus components we recommend the use of our special NESimplavit® broaches of the correct size is mandatory.
5) Correct axial and rotational alignment of the implant is of major importance. Otherwise subluxation, dislocation and/or breakage of the prosthesis may occur.
6) Care is to be taken to assure stable fixation, and to avoid interference with the proper seating of the components.
7) Prior to closure, the surgical site should be thoroughly cleaned of the bone chips, extraneous cement, ectopic bone, etc. Foreign particles at the metal-plastic interface may cause excessive wear and/or friction.

Postoperative
1) Postoperative patient care, detailed instructions and warnings by the physician are of major importance. To enhance the healing process an external support of the operated arm is recommended for a limited period of time.
2) Active and passive movement must be carried out with extreme caution.
3) Postoperative therapy should support the healing process and prevent the arm from being submitted to excessive stress.
4) Patients are to be reminded repeatedly of the necessity to reduce activity as recommended by their physician.

Special user information
Never reuse implants which have already been implanted or removed, even if they appear undamaged (danger of implant breakage due to internal material fatigue).

Packaging and labelling
Each of the NESimplavit® implants and instruments is packaged separately. They should only be accepted by hospitals and physicians if supplied in their original packaging and with an original label. For reasons of safety, protection and identification all implants should always be kept in cool and dry environment in their unopened packagings.

Sterilization
The implants of the NESimplavit® system have been sterilized by gamma irradiation (min. 25kGy) in vaccuum and are supplied in protective covers. Please always check the packages for perforation or other damage prior to surgery.
Resterilization of PE-components is not permitted.
For further information please refer to:

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