MUTARS®

implantcast

MUTARS® Xpand

non-invasive growing prosthesis

C-Fit 3D®
customized planning & production

MUTARS® Xpand
non-invasive growing prosthesis

MUTARS® was developed in co-operation with
Prof. Dr. W. Winkelmann (former director)
and Prof. Dr. G. Gosheger (director), Clinic and
Polyclinic for General Orthopedics and Tumororthopedics
at the University Hospital of Münster, Germany.
MUTARS® Xpand was developed in co-operation with Prof. Dr. R. Baumgart,
director of the Limb Lengthening Center Munich, Germany.
MUTARS® has been in successful clinical use since 1992.

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Remark: All components of the MUTARS® Xpand prosthesis are customised implants which are planned, designed and manufactured for each patient based on a scaled x-ray.

Introduction

Since it's introduction in 1992 the MUTARS® (**M**odular **U**niversal **T**umour **A**nd **R**evision **S**ystem) has been successfully used for the treatment of major osseous defects of the lower and upper extremities. Its modular design was developed in cooperation with Univ.-Prof. Dr. W. Winkelmann (em. Director) and Univ.-Prof. Dr. G. Gosheger (Director), Department of General Orthopaedics and Orthopaedic Oncology at the University Hospital of Münster, Germany. The system has achieved good functional results and provides the surgeon with an individualised solution for major osseous defects, while bearing in mind the potential need for subsequent replacement of adjacent joints.

Endoprosthetic treatment of tumour patients represents a challenge for the surgeon and for the implant system. This is especially true when treating pre-adolescent patients as intramedullary implant fixation, while being stable, leads to reduced growth of the treated extremity / limb length discrepancy. Most commercially available systems include lengthening modules which are elongated mechanically during surgical procedures. In order to reduce the exposure of the patients to several surgeries and rising the risk of infection, the MUTARS® Xpand prostheses follow a new concept. Based on an idea of Prof. Dr. R. Baumgart (Limb Lengthening Center Munich, ZEM-Germany) and in close collaboration with the company WITTENSTEIN intens GmbH (Igersheim) two new product systems (mechanical and biological) of growing prostheses have been developed: **MUTARS® Xpand and MUTARS® BioXpand.**

MUTARS® Xpand

The MUTARS® Xpand system was developed in order to provide an adequate treatment for children who suffer from deficiencies of the lower or upper extremities as a result of oncological disorders. All of the components in MUTARS® Xpand range are customised implants which are planned, designed and manufactured for each individual patient based on a scaled x-ray. The purpose of the implant (aside from the preservation of the arm and/or leg itself) is to allow future non-surgical limb length corrections.

The elongation of the MUTARS® Xpand Prosthesis

The mechanical, non-invasive growing modules of the MUTARS® Xpand use a miniaturized, mechatronic actuator inside the prosthesis which is controlled by an extracorporeal energy coupling. Hence invasive lengthening surgeries may be avoided, reducing the risk of infection. After the lengthening process the Xpand components need to be replaced by regular MUTARS® components.

MUTARS® BioXpand

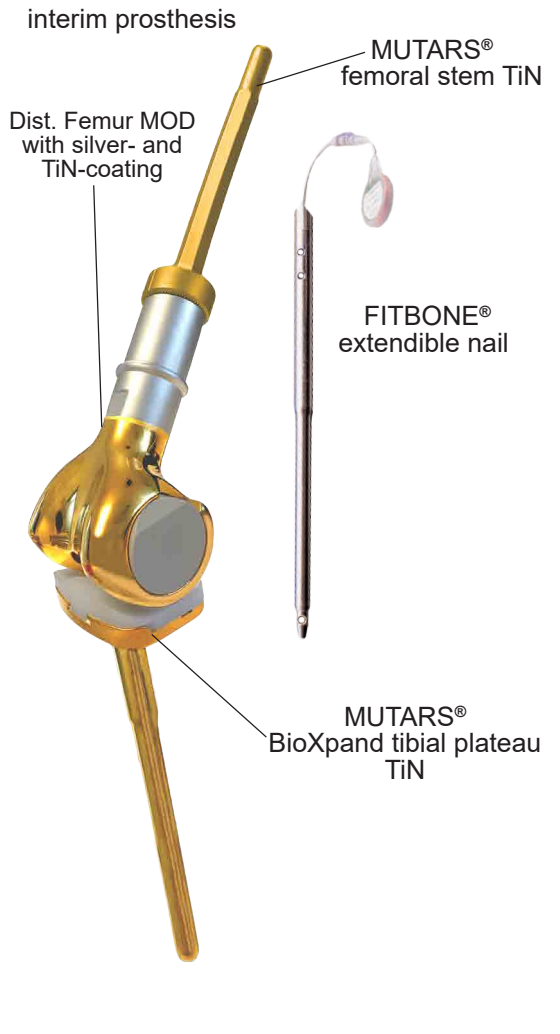
The "biological" MUTARS® BioXpand growing prosthesis utilises an interim implant in the first instance. This will later be replaced by a lengthening nail (FITBONE®) when lengthening is actually required. Here the electromagnetic motor technology is used in a way which lengthens the bone of the patient so as to gain bone stock.

The lengthening of the remaining bone, using the MUTARS® BioXpand Prosthesis

The "biological", non-invasive BioXpand growing prosthesis is indicated for use in the proximal femur, the distal femur as well as the proximal tibia and is intended to simulate bone growth of remaining bone stock post tumour resection. Using the principles of callus distraction (Page 5, Fig. 1 to 3) the interim prosthesis is replaced by a tumor prosthesis combined with a motorised lengthening nail (FITBONE®), an osteotomy is performed and the remaining bone can be lenghtened. After the lengthening procedure the MUTARS® BioXpand components need to be replaced by conventional MUTARS® components.

NB: All components of the MUTARS® BioXpand growing prosthesis are customised implants. The lengthening treatment itself is undertaken via consultation with Prof. Dr. R. Baumgart, ZEM-Germany in München.

MUTARS® BioXpand - Principle of the callus-formation



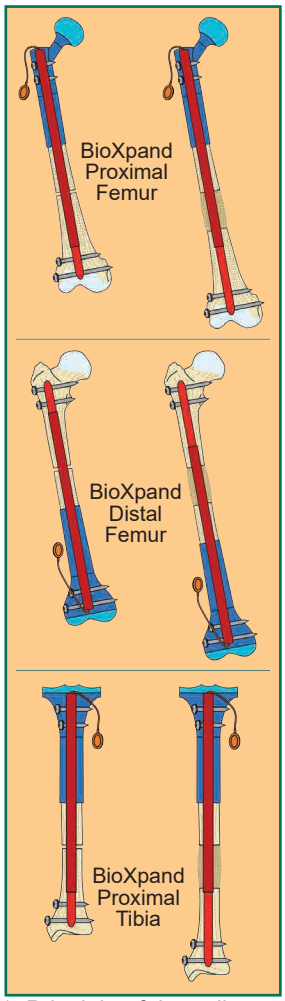


Fig. 1: Principle of the callus-formation with BioXpand

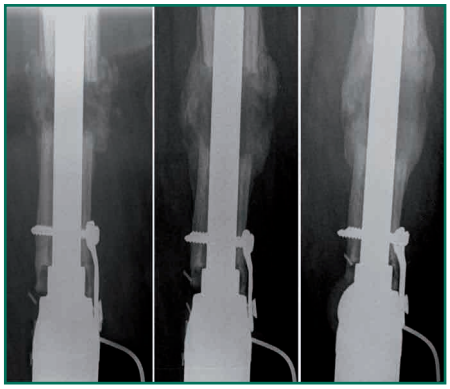


Fig. 2: Steps of callus formation (ZEM-Germany)

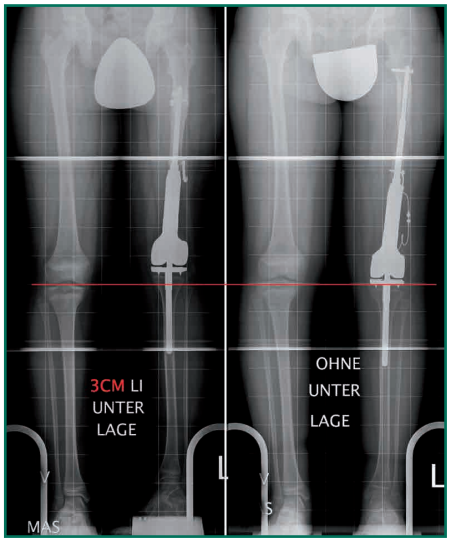


Fig. 3: Leg lengthening of 3cm with the BioXpand prosthesis (ZEM-Germany)

Most of the MUTARS® components can be coated with silver and TiN (titanium nitride). For further information please consult the MUTARS® brochure (REF: MUTOVERE).

MUTARS®Silver

In recent years, because of the antimicrobial effect of silver ions, the CE certified MUTARS® Silver components have become the standard option for the treatment of tumour patients in several major tumour centers throughout Europe and to date more than 12,500 successful MUTARS® Silver implantations have been performed.

TiN-coating (ceramic)

The biocompatible TiN coating reduces the release of metall ions to a minimum and hence is especially suitable for patients with sensitivity to cobalt, chrome and nickel. Additionally, the ceramic TiN coating improves abrasion resistance because ceramic coatings have a higher hardness grade, scratch and corrosion resistance compared to standard uncoated metals. The TiN-coating on MUTARS® components has been used successfully in the clinical setting for over 20 years.

MUTARS® Xpand product characteristics

The MUTARS® Xpand modular prosthesis is telescopic and offers the option of lengthening via wireless energy transmission. An electric motor (and receiver), called TAM, is built into the prosthesis which is controlled by an extracorporeal control unit (and electromagnetic energy transmitter). Lengthening itself is done non-surgically in 0.035mm steps without the risk of vascular injury, nerve injury and for that matter anaesthetic incident.

Planning of a MUTARS® Xpand prosthesis

The growing prosthesis can either be implanted in one stage surgery if a limb length discrepancy is already existent, or in a second procedure after a length discrepancy presents. The potential elongation of the prosthesis varies between 50mm and 100mm dependent on the resection length. In order to develop a detailed plan it is essential to have scaled x-rays, to know the exact resection length and to decide whether a one or a two stage surgery is indicated.

One stage surgery

In this instance, after tumour resection, the definitive / functional TAM (as opposed to the dummy TAM) is implanted during this, the first, surgery. The prosthesis is immediately ready for use. The advantage of this procedure is that no additional surgery is needed to implant the engine of the prosthesis. The disadvantage however is that because of the relatively long idle time it is possible that the TAM won‘t work properly when needed. Reasons for this could be the ingrowth of soft tissue which prevents the TAM from elongating, or damage to the cable of the receiver through scar tissue and/or trauma. Also if the placement of the receiver is too deep it might interfere with the signal from the transmitter.

Two stage surgery

Here, after tumour resection, the appropriate length of dummy TAM (as opposed to the definitive / functional TAM) is implanted. Once the patient has recovered sufficiently and a length discrepancy has presented, the same length functional / definitive TAM is implanted during a second surgical procedure. Lengthening can then be started once wound healing has taken place. The advantage of a two stage approach is that the potential for tissue ingress within and / or mechanical damage to the TAM are less likely to occur as the TAM will be implanted for a shorter period of time before deployment. These advantages do however need to be balanced against the need for an additional surgery.

Lengthening process

Lengthening of no more than 1mm / day is undertaken according to the protocols of the manufacturer (WITTENSTEIN intens GmbH). If soft tissue / extension problems should occur then the process can of course be interrupted at any time. Care should be taken not to exceed the maximum stroke of the TAM. The lengthening at every stage has to be checked via confirmation x-rays. Also of the number of induced electromagnetic impulses should be documented.

Termination of lengthening

As stated previously, lengthening may only be performed until the maximum stroke of the TAM is reached as exceeding this limit can lead to the collapse of the TAM itself. The maximum number of impulses can be found in the product specification and the MUTARS® Xpand user information. The TAM should be removed promptly after the termination of the prosthesis lengthening. The prosthesis is to be replaced by one more suited for skeletally mature adults as soon as possible after the patient's growth phase is complete.

Maximal load of the prosthesis

This prosthetic system is intended for use in children and it has been made as slim as possible hence the mechanical load carrying capacity is, quite naturally, limited. However both the TAM as well as the prosthesis have been load tested and they meet ISO 7206-4 criteria for hip prosthesis so full weight bearing is possible for patients of up to 40 kg. For patients heavier than 40 kg partial weight bearing (via the use of crutches for example) is recommended for as long as the motor is in-situ.

Patients are to be informed that high levels of physical activity can negatively influence the longevity of the prostheses.

MUTARS® Xpand Proximal Femur

MUTARS® Xpand Proximal Femur

Indication:
Tumours or other major bone defects in growing children and youths in the area of the proximal femur including hip joint arthroplasty as hemi prosthesis or total hip replacement

System components:
MUTARS® Xpand Proximal Femur incl. accessory kit,
MUTARS® Xpand extension piece,
MUTARS® Xpand reducer piece,
MUTARS® Xpand bar screw,
MUTARS® Xpand femoral stem cementless,
MUTARS® TAM*, receiver 12V*

*those components are manufactured by WITTENSTEIN intens GmbH

Length of reconstruction and possible elongation:
180mm → 50mm
205mm → 75mm
230mm → 100mm

Materials:
implatan®; $TiAl_6V_4$

MUTARS® Xpand Distal Femur

MUTARS® Xpand Distal Femur

Indication:
Tumours or other major bone defects in growing children and youths in the area of the distal femur with major femoral bone loss

System components:
MUTARS® Xpand Distal Femur incl. accessory kit,
MUTARS® tibial joint f. hinged knee incl. locking bolt,
MUTARS® Xpand PE-inlay for hinged knee,
MUTARS® Xpand extension piece,
MUTARS® Xpand reducer piece,
MUTARS® Xpand bar screw,
MUTARS® Xpand femoral stem cementless,
MUTARS® TAM*, receiver 12V*

*those components are manufactured by WITTENSTEIN intens GmbH

Length of reconstruction and possible elongation:
170mm → 50mm
195mm → 75mm
220mm → 100mm

Materials:
implatan®; $TiAl_6V_4$, implavit®; CoCrMo, UHMW-PE

MUTARS® Xpand Proximal Tibia

MUTARS® Xpand
femoral joint

MUTARS® Xpand
PE-inlay for hinged knee

Receiver 12V

MUTARS® Xpand
proximal tibia

MUTARS® Xpand
tibial stem cementless

MUTARS® Xpand Proximal Tibia

Indication:
Tumours or other major bone defects in growing children and youths in the area of the proximal tibia with major femoral bone loss

System components:
MUTARS® Xpand femoral joint incl. axle,
MUTARS® Xpand proximal tibia incl. accessory kit,
MUTARS® Xpand PE-inlay for hinged knee,
MUTARS® Xpand extension piece,
MUTARS® Xpand reducer piece,
MUTARS® Xpand bar screw,
MUTARS® Xpand tibial stem cementless,
MUTARS® TAM*, receiver 12V*

*those components are manufactured by WITTENSTEIN intens GmbH

Length of reconstruction and possible elongation:
170mm → 50mm
195mm → 75mm
220mm → 100mm

Materials:
implatan®; $TiAl_6V_4$, implavit®; CoCrMo, UHMW-PE

MUTARS® Xpand Prox. Humerus

MUTARS® Xpand
humeral cap

MUTARS® Xpand
prox. humerus

MUTARS® Xpand
humerus stem cementless

MUTARS® Xpand Proximal Humerus

Indication:
Tumours or other major bone defects in growing children and youths in the area of the proximal humerus with major humeral bone loss

System components:
MUTARS® Xpand humeral cap
MUTARS® Xpand prox. humerus
MUTARS® Xpand humerus stem cementless
MUTARS® TAM*, receiver 12V*

*those components are manufactured by WITTENSTEIN intens GmbH

Length of reconstruction and possible elongation:
approx. 140mm → 50mm

Materials:
implatan®, $TiAl_6V_4$

MUTARS® Xpand Implants

***N**: Implants are available with TiN-coating!

MUTARS® Xpand Proximal Femur*N incl. accessory kit

mat.: implatan® with TiN coating

5710-1170 170mm
5710-1190 195mm
5710-1220 220mm

MUTARS® Xpand Proximal Femur accessory kit

5720-8103
(included also in the packages described above)
screw, cover screw

MUTARS® Xpand motor dummy TAM 1650 / 1675 / 16100

5720-8200	TAM 1650	50mm
5720-8201	TAM 1675	75mm
5720-8202	TAM 16100	100mm

Note:
Please notice that the amount of implants and instruments sent with any individual shipment may differ from the information provided in this brochure. Please make sure, during the preoperatively planning, that all necessary implants and instruments are available for the surgery.

All MUTARS® Xpand implants are custome-made. The mentioned REF numbers are examples that describe the general specification. The special design of the implants is determined individually and may lead to different REF numbers.

MUTARS® Xpand Implants

MUTARS® Xpand Distal Femur*N
incl. accessory kit
mat.: implatan® with TiN-coating
5720-7160 left 160mm
5720-7185 left 185mm
5720-7210 left 210mm
5720-6160 right 160mm
5720-6185 right 185mm
5720-6210 right 210mm

MUTARS® tibial joint for hinged knee
incl. locking bolt
mat.: implavit®
5720-8210

MUTARS® Xpand Distal Femur
accessory kit
5720-8101 left
5720-8100 right
(including in the kit: screw, cover screw, axle, PE cover)

MUTARS® Xpand PE-inlay for hinged knee
mat.: UHMW-PE
5721-0005

MUTARS® Xpand Implants

MUTARS® Xpand femoral joint*N
incl. axle
mat.: implatan® with TiN coating, implavit®
5720-2105 left
5720-2110 right

MUTARS® Xpand proximal tibia*N
incl. accessory kit
mat.: implatan® with TiN coating
5720-4160 160mm
5720-4185 185mm
5720-4210 210mm

MUTARS® Xpand proximal tibia
accessory kit
5720-8102 (included also in the packages described above)
bolt, screw, cover screw

MUTARS® Xpand PE-inlay for hinged knee
mat.: UHMW-PE
5721-0005

MUTARS® Xpand Implants

MUTARS® Xpand extension piece
mat.: implatan®

5772-8304	40mm
5772-8306	60mm
5772-8308	80mm

MUTARS® Xpand reducer piece
mat.: implatan®

5730-8220	20mm
5730-8230	30mm

MUTARS® Xpand bar screw
mat.: implatan®

5720-8015	M10x 15mm
5720-8055	M10x 55mm
5720-8075	M10x 75mm
5720-8095	M10x 95mm

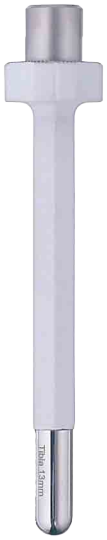
MUTARS® Xpand femoral stem cementless
mat.: implatan® with HA coating

REF	diameter	length
5720-8110	10mm	120mm
5720-8111	11mm	120mm
5720-8112	12mm	120mm
5720-8113	13mm	120mm
5720-8114	14mm	120mm
5720-8115	15mm	120mm
5720-8116	16mm	120mm
5720-9110	10mm	90mm
5720-9111	11mm	90mm
5720-9112	12mm	90mm
5720-9113	13mm	90mm
5720-9114	14mm	90mm
5720-9115	15mm	90mm
5720-9116	16mm	90mm

MUTARS® Xpand Implants

MUTARS® Xpand tibial stem cementless
mat.: implatan® with HA coating

REF	diameter	length
5720-8310	10 mm	120mm
5720-8311	11 mm	120mm
5720-8312	12 mm	120mm
5720-8313	13 mm	120mm
5720-8314	14 mm	120mm
5720-8315	15 mm	120mm
5720-8316	16 mm	120mm
5720-9310	10 mm	90mm
5720-9311	11 mm	90mm
5720-9312	12 mm	90mm
5720-9313	13 mm	90mm
5720-9314	14 mm	90mm
5720-9315	15 mm	90mm
5720-9316	16 mm	90mm



MUTARS® TAM*

6000-0870	1650	50mm
6000-0885	1675	75mm
6000-0886	16100	100mm

*manufactured by WITTENSTEIN intens GmbH

receiver 12V*
6000-1615
*manufactured by WITTENSTEIN intens GmbH

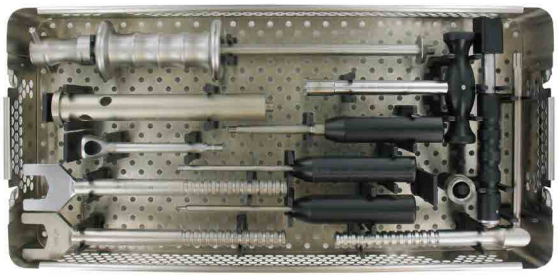
MUTARS® Xpand Instruments

torque wrench (sterile)
6000-1622

Raucodrape® (sterile)
6000-1562

stethoscope (non-sterile)
6000-0676

MUTARS® Xpand control unit
incl. transmitter head (non-sterile)*
6000-1524 (controll unit + transmitter head)
6000-1365 (only control unit)
6000-1149 (only transmitter head)
*manufactured by WITTENSTEIN intens GmbH



MUTARS® Xpand basic container
7999-5780

MUTARS® Xpand femoral rasp container
7999-5782

material and coating catalogue

materials:

implatan®; $TiAl_6V_4$	acc. to	ISO 5832-3
implavit®; CoCrMo	acc. to	ISO 5832-4
implavit®; CoCrMo	acc. to	ISO 5832-12
UHMW-PE	acc. to	ISO 5834-2

coatings:

implaFix® HA; HA-coating	acc. to	ISO 13779-2

TiN-coating (titanium nitride coating)

Notes

Notes

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