Instructions for Use

IOT MODULAR ENDOPROSTHESIS SYSTEM

Legend of Symbols Used in the Packages

REF	Product Code
LOT	Batch Number
	See Use Instructions
Material Ti / Al / V	Ti / Al / V (ASTM F136) Alloy
	Date of Manufacturing
Sterile **R**	Sterilized by Gamma Radiation
	Date of Manufacturing

	Avoid direct exposition to sunlight
	Protect from Humidity
	Caution - Fragile
	Do not use if package is violated
	Single use product
	Due Date

DESCRIPTION:

Non Conventional System for Knee is composed by modules of several sizes and shapes manufactured in titanium alloy, according to ASTM F136 technical specification, with the purpose of substituting articulations and bony parts, mainly affected by tumors.
It is a modular system and its components are presented in a variety of sizes that allow the assembly of configurations best suitable for treatment of the fracture.

Composition:

The components of the Non Conventional System for Knee are manufactured in Titanium Alloy according to the requirements of the specification rules ASTM F136 - Specifications for Wrought Alloy of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) R56401 for application in Surgical Implants. (Standard Specification for Wrought Titanium-6Aluminum -4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications).

Part of the Articulated Knee, the Tibial Component and the Plateau are manufactured in polyethylene of ultra-high molecular weight (UHMWPE), according to the specification rule NBR ISO 5834-2.

Purpose:

Non Conventional System for Knee has for purpose to substitute the articulation and bony parts of the Knee, mainly affected by tumors.

The incorrect selection, placement, positioning and fixation of the implant can cause not desirable results. The surgeon should be familiarized with the material, the application method and the surgical procedure before the surgery.

The system should not be used in case there is no good bony support to assure the stability of the implant. In these circumstances, supplementary methods of bony grafting should be used together, be it autologous or homologous, or yet, with the help of screens and accessories.

The success of the consolidation is tied up to the correct selection, positioning, selection and fixation of the implants, and is under the doctor's responsibility, who evaluates the patient and decides which materials should be used. The success is also linked to the rigorous fulfillment of the postoperative cares recommended by the doctor.

Important: The products here described were developed for use in the circumstances above described, so that any other use is considered contraindicated or without scientific substratum to support such use.

Forms of Presentation:

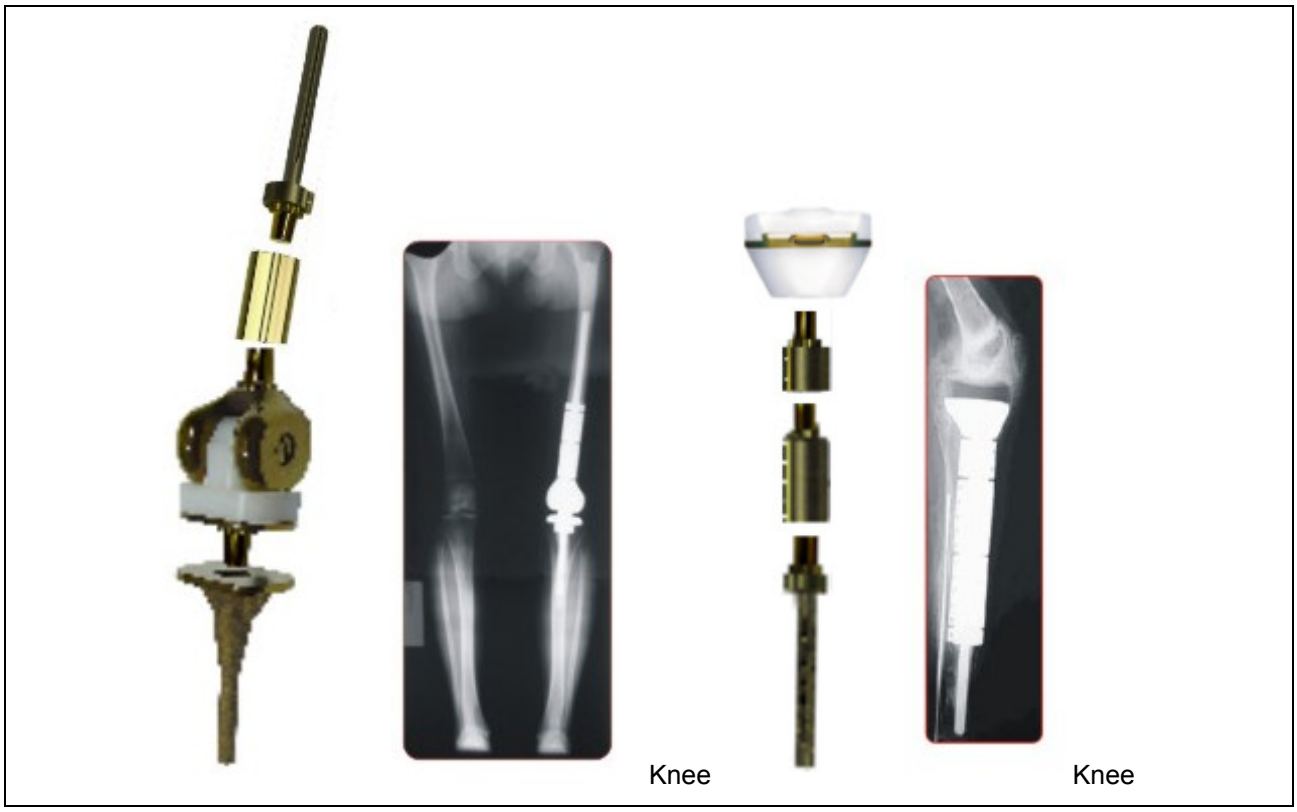
1. **Non Conventional System for Knee is composed of the following components:**

Table – IOT Modular Endoprosthesis

CODE	DESCRIPTION
04.07.50.00000	IOT Modular Endoprosthesis Articulated Knee Cone 12/14 Ti
04.07.50.00001	IOT Modular Endoprosthesis Articulated Knee Cone 12-14 Ti – Small
04.07.51.00054	IOT Modular Endoprosthesis Proximal Tibial Component Cone 12/14 Ti 54 mm
04.07.51.00059	IOT Modular Endoprosthesis Proximal Tibial Component Cone 12/14 Ti 59 mm
04.07.51.00064	IOT Modular Endoprosthesis Proximal Tibial Component Cone 12/14 Ti 64 mm
04.07.51.00069	IOT Modular Endoprosthesis Proximal Tibial Component Cone 12/14 Ti 69 mm
04.07.40.08045	IOT Modular Endoprosthesis Stem Cone 12/14 Ti 8 x 45 mm
04.07.40.08070	IOT Modular Endoprosthesis Stem Cone 12/14 Ti 8 x 70 mm
04.07.40.08095	IOT Modular Endoprosthesis Stem Cone 12/14 Ti 8 x 95 mm
04.07.40.09045	IOT Modular Endoprosthesis Stem Cone 12/14 Ti 9 x 45 mm
04.07.40.09070	IOT Modular Endoprosthesis Stem Cone 12/14 Ti 9 x 70 mm
04.07.40.09095	IOT Modular Endoprosthesis Stem Cone 12/14 Ti 9 x 95 mm
04.07.40.10045	IOT Modular Endoprosthesis Stem Cone 12/14 Ti 10 x 45 mm
04.07.40.10070	IOT Modular Endoprosthesis Stem Cone 12/14 Ti 10 x 70 mm
04.07.40.10095	IOT Modular Endoprosthesis Stem Cone 12/14 Ti 10 x 95 mm
04.07.40.11095	IOT Modular Endoprosthesis Stem Cone 12/14 Ti 11 x 95 mm

04.07.40.11130	IOT Modular Endoprosthesis Stem Cone 12/14 Ti 11 x 130 mm
04.07.40.11160	IOT Modular Endoprosthesis Stem Cone 12/14 Ti 11 x 160 mm
04.07.40.12095	IOT Modular Endoprosthesis Stem Cone 12/14 Ti 12 x 95 mm
04.07.40.12130	IOT Modular Endoprosthesis Stem Cone 12/14 Ti 12 x 130 mm
04.07.40.12160	IOT Modular Endoprosthesis Stem Cone 12/14 Ti 12 x 160 mm
04.07.40.12180	IOT Modular Endoprosthesis Stem Cone 12/14 Ti 12 x 180 mm
04.07.40.12200	IOT Modular Endoprosthesis Stem Cone 12/14 Ti 12 x 200 mm
04.07.40.12250	IOT Modular Endoprosthesis Stem Cone 12/14 Ti 12 x 250 mm
04.07.40.14095	IOT Modular Endoprosthesis Stem Cone 12/14 Ti 14 x 95 mm
04.07.40.14130	IOT Modular Endoprosthesis Stem Cone 12/14 Ti 14 x 130 mm
04.07.40.14160	IOT Modular Endoprosthesis Stem Cone 12/14 Ti 14 x 160 mm
04.07.40.14180	IOT Modular Endoprosthesis Stem Cone 12/14 Ti 14 x 180 mm
04.07.40.14200	IOT Modular Endoprosthesis Stem Cone 12/14 Ti 14 x 200 mm
04.07.40.14250	IOT Modular Endoprosthesis Stem Cone 12/14 Ti 14 x 250 mm
04.07.52.11130	IOT Modular Endoprosthesis Fem. Stem w/ Anti-curvato Cone 12/14 Ti 11x 130 mm
04.07.52.12130	IOT Modular Endoprosthesis Fem. Stem w/ Anti-curvato Cone 12/14 Ti 12x 130 mm
04.07.52.13130	IOT Modular Endoprosthesis Fem. Stem w/ Anti-curvato Cone 12/14 Ti 13x 130 mm
04.07.52.14130	IOT Modular Endoprosthesis Fem. Stem w/ Anti-curvato Cone 12/14 Ti 14x 130 mm
04.07.42.12095	IOT Modular Endoprosthesis Stem Right/Left Cone 12/14 Ti 12 x 95 mm
04.07.43.00000	IOT Modular Endoprosthesis Tibial Base Cone 12/14 Ti
04.07.43.00001	IOT Modular Endoprosthesis Tibial Base Cone 12 –14 Ti – Small
04.07.36.00040	Support Ring for Stem Ti Ø 2 x 40 mm
04.07.36.00046	Support Ring for Stem Ti Ø 2 x 46 mm
04.07.36.00052	Support Ring for Stem Ti Ø 2 x 52 mm
04.07.44.00025	IOT Modular Endoprosthesis Intermediary Component Cone 12/14 Ti 25 mm
04.07.44.00050	IOT Modular Endoprosthesis Intermediary Component Cone 12/14 Ti 50 mm
04.07.44.00100	IOT Modular Endoprosthesis Intermediary Component Cone 12/14 Ti 100 mm
04.07.47.00045	IOT Modular Endoprosthesis Diaphisary Component Internal Cone 12/14 Ti 45 mm
04.07.48.00025	IOT Modular Endoprosthesis Diaphisary Component External Cone 12/14 Ti 25 mm
04.07.49.00048	IOT Modular Endoprosthesis Angular Comp. Right/Left Cone 12/14 Ti 48 mm
04.07.23.00054	Tibial Plateau Endoprosthesis 54mm
04.07.23.00057	Tibial Plateau Endoprosthesis 57mm
04.07.23.00059	Tibial Plateau Endoprosthesis 59mm
04.07.23.00062	Tibial Plateau Endoprosthesis 62mm
04.07.23.00064	Tibial Plateau Endoprosthesis 64mm
04.07.23.00067	Tibial Plateau Endoprosthesis 67mm
04.07.23.00069	Tibial Plateau Endoprosthesis 69mm
04.07.23.00072	Tibial Plateau Endoprosthesis 72mm

2. **Demonstration of forms of implantation of the system:**



To implant Non Conventional System for Knee it is necessary to use specific instrumental to be acquired separately from the implants.

The Instrumental Kit for Application of Non Conventional System for Knee is registered at Anvisa under nº 10417940064.

Contact MDT representative to obtain more information reference the instrumental.

The Instrumental Kit for Application of Non Conventional System for Knee is composed of the following items:

Table – Instrumentals

DESCRIPTION
Wire Guide
Intramedular Milling Cutter w/T Cable p/IOT Tibial Base
Final Impactor
Module Extrator
Head Tester
Intramedular Tibial Drill Guide
Reducer for IOT Tibial Milling Cutter Guide
Diaphisary Milling Cutter
Stem Impactor
Tibial Channel Moulder
Hammer

Base for Impactor
Flexible Drill
Screw-driver for Articulate Module
Impactor for Articulated Knee

The surgical instruments are subject to wear with normal usage and may break. The surgical instruments are only to be used for their intended purposes. All surgical instruments are to be regularly inspected for wear and damage.

The surgical instruments are to be acquired separately, but always from the same manufacturer of the implant.

The instrumentals are supplied uncontaminated, but not sterilized. They are supplied with the following information engraved:

- Product Code
- Batch Number
- Logotype of the Company

CONTRAINDICATION

Non Conventional System for Knee is contraindicated to the following patients:

- Young or sports activities performers;
- Patients weighing above 102 kilos;
- Patients presenting infectious pathology previous or present;
- Patients presenting dementia
- Patients presenting sensibility to strange bodies.
- Poor bony quality.
- Patients in general poor condition, and due to that, unable to undergo an operation.
- Patients with bony infection, be it intense or chronic (relative contraindication, left to doctor's discretion).

The use in the above mentioned situations can cause precocious loosening of the component, due to excess of mechanical claiming, infection or prosthetic luxation.

ADVERSE EFFECTS

In addition to the fact that obvious risks can happen in the presence of orthopedic implants, like failure, loosening and fractures, the following risks of tissular adverse answers and possible complications should be presented and discussed with the patient:

- Absence or union delay that will result in rupture of the implant.
- Deformation or fracture of the implant.
- Loosening or dislocation of the implant.
- Sensibility to metals or reaction to strange body.
- Pain or discomfort caused by the product.

- Injury to nerves provoked by surgery.
- Bony or soft tissues necrosis.
- Inadequate recovery, and
- Bone fractures and postoperative pain.
- Although there is not a connection scientifically proved reference the use of orthopedic implants with the characteristics of the materials used and the occurrence of cancer, any risks and uncertainties reference long terms effects of joint substitution, should be discussed with the patient previously to the surgery.
- Cancerous tissue found next to implants can be related to factors not linked directly to the implant itself, such as: lung primary tumor metastasis, breast, digestive system and other, or also due to implantation of cancerous cells which can happen during surgical procedures or diagnostics like biopsy, or still, resulting from progression of Paget´s disease.
- The implantation of strange material to organic tissue can result in inflammatory reactions, which can happen, for example, as answer to the presence of debris arose from implants (like metallic or polyethylene debris), which can cause histiocytic answer, granuloma of strange body type, which can cause bony destruction, associated or not to the loosening of the implant.

PRECAUTIONS

- Non Conventional System for Knee should not be used in case there is no good bony support to assure the implant stability. In these circumstances, supplementary methods of bone grafting are to be used, be it autologous or homologous, or yet, with the help of a reinforcement screen.
- Bony necrosis induced by irradiation in consequence of radiotherapy due to cancer treatment is relative contraindication to articular substitution, once the lack of bony support can lead to premature loosening of the implant. In this case, other techniques and implantation systems should be used.
- It is advisable the use of preventive antibiotic therapy in patients carriers of articular substitutions which are submitted to proceedings that can cause transitory bacteremia (odontological procedures, endoscopy, groin vessel catheterism and other minor surgical proceedings).
- Non Conventional System for Knee was conceived to be implanted through the use of instrumental specially developed for that purpose. The instrumental box contains the instruments necessary for insertion and adequate positioning of the implant. Any improvisation with different instrumental or inaccurate surgical technique can jeopardize the fixation quality and/or the implant positioning.
- Previously to insertion of the component, it is advisable to obtain medullar cavity free of debris, with viable bony bed. In some occasions, reinforcements under the form of bony grafts or contention and support devices are indicated to reestablish the bony reserve and guarantee a good stability of the implant.
- It is not advisable to use the product (in direct contact) together with implants of other manufacturers, even though the specifications are similar, because there can be dimensional incompatibility problems.
- **SINGLE USE PRODUCT – DO NOT REUSE**
- **Non Conventional System for Knee is supplied sterile by Gamma Radiation.**

- Use immediately after the opening of the sterilization stamp.
- Discard and **DO NOT USE** opened or damaged devices. Use only devices that are packed in shut and non damaged packages.
- **DO NOT USE** in case of loss of sterility of the device.
- **DO NOT RE-STERILIZE**.

THE PATIENT SHOULD BE INFORMED OF:

- All the restrictions after surgery, mainly the ones related to sports and occupational activities.
- The fact that complications or failures arisen from the total knee arthroplasty are much common to occur in:
  - patients with functional expectations beyond the ones offered by the articular substitution;
  - patients with high corporal weight, especially above 102 kilos;
  - young and/or dynamic patients;
  - patients with small ossature.

- It is necessary a periodic medical evaluation to observe possible alterations in the implant and in the adjacent bone. Without such evaluation it will not be possible to detect loosening of components or the occurrence of Osteolysis;
- If a revision surgery is not made in case there is release of the components, it can occur progressive loss of periprosthetic bony reserve.
- The implants interfere in the results of Magnetic Resonance exam. Metallic implant carriers should inform being implant carrier when submitted to such exams.
- The patient should be advised that the product does not substitute as well as does not have the same performance of a normal bone and, therefore, can break, lose its shape or release due to excess of activity, precocious loading, etc.;
- The patient should also be informed that any circumstances that take to chronic tissular damage can be oncogenic.
- The complications related to Knee total arthroplasty, listed in the topic **Adverse Effects** and the information listed in the topics: **Indications, Contraindications, Precautions and Warnings.**

WARNING

- Discard and do not use open or damaged devices. Use only devices packed in shut and non damaged packages.
- The proper handling of this material is responsibility of the qualified personnel.
- The patient should be periodically submitted to medical evaluation to check the implant and bony conditions.
- Do not use the product if its term is due or its package is violated.
- Inadequate sterilization of the surgical instrumental can cause prosthetic infection.
- Observe rigorously the product identification. It is not allowed to mix implants and/or instrumental of other source or purpose.

- The clinical results and the durability of the implant are extremely dependent on the application of an accurate surgical technique.
- The resistance limit of the implant, that varies according to its type should be respected, otherwise there will be the risk of weakness and possible fracture of the material.
- Single use hospital/medical product – destroy after removal of the product.
- Never reuse an implant. Even though it may not present any external damage, early activities can reduce its durability.
- Date of manufacturing, due date and batch number: see product label.

Instructions for Use

The surgery techniques vary according to the surgeon, who will choose the surgery method, type and dimension of the products to be used, as well as the criterion for evaluation of the surgery results.

- Manipulate the components of Non Conventional System for Knee exclusively in proper environment (ambulatory or surgical rooms) taking adequate manipulation care (use of sterilized gloves). Only qualified professionals should manipulate and implant the Non Conventional System for Knee.
- Non Conventional System for Knee should be adapted and applied taking into consideration the exigencies and proper surgical techniques.
- The clinical results and the durability of the implant are extremely dependent of the tridimensional alignment of the components, being, therefore, essential to apply a precise surgical technique.
- Do not use Non Conventional System for Knee together with products of other brands, because there can be incompatibility problems among the materials.

Sterilization

Note: Sterile supplied product; therefore, the integrity of the package should be observed. Do not use the product if the package is violated.

STERILE SUPPLIED PRODUCT – Gamma Ray

Cleaning and Sterilization of the Instrumentals

Importante
Detergents with free chlorine or sodium hydroxide **should not be used**.

When the instrumentals are used for the first time, they should be removed from their packages, cleaned with 70% medical alcohol + 30% distilled water.

After cleaned, the products should be rinsed with sterilized water and dried with a clean cloth that does not release fibers.

Sterilization

Before surgical use, the instrumentals should be cleaned as described above and sterilized by autoclave. The sterilization does not substitute the cleaning of the material, and a dirty material will never reach sterilization.

Sterilizing by Autoclave is a safe process; however, if there is no control of the operational parameters, the instrumental can be damaged:

Humidity+high temperature+Oxygen=corrosion=micro-fissure=crackle=breakage

The chosen sterilization process should attend to Rule EN556 that establishes that the theoretical probability of the presence of vital microorganisms is, at the most, equal to 1 over 10^6 (S.A.L. [Sterility Assurance Level] sterility assurance level =10^6).

For cleaning and sterilizing, the proper proceedings should be observed. Use Rule ASTM F1744: 1996 as suggestion.

The recommended sterilization cycle is:

Method	**Cycle**	**Temperature**	**Time of Exposition**
Steam	Pre-vacuum	132^0 - 135^0 C	Minimum
		[270^0 - 275^0F]	10 minutes

Inspection

1 -) Check if the instruments present signs of wear and damage in all handling stages.

2 -) If any damage is detected, a representative of MDT Indústria Comércio Importação e Exportação de Implantes SA should be contacted for orientation.

Risk of Contamination

Considering that the implantable components enter into contact with tissue and corporal fluids, there is the risk of biological contamination and transmission of diseases such as Hepatitis and HIV etc. Therefore, removed products should be treated as potentially contaminant materials.

Discarding of the Product

The product can be damaged if it falls or crushes over hard surfaces. The product integrity should be inspected when opening the package. Do not use the product if any abnormality is observed.

Discard the implants removed from patients. **They should not be reused**.

The implants removed or defective due to accidents should be destroyed before being discarded. We recommend that the parts are cut, bent or filed to avoid their reuse.

To discard the removed components of Non Conventional System for Knee, follow the legal procedures for discarding of products potentially contaminants, in force in the country.

The material removed should be considered potentially contaminant, and as any residue of hospital origin, specific discarding precautions should be observed for that type of material.

Tracking

To assure tracking of the implanted product and fulfill the Sanitary Authority requirements, we recommend that the surgeon responsible for the implant, reports to the Distributor the following information reference the implanted product, patient and the surgery made:

- Name of the Surgeon
- Date of Surgery
- Name of the Patient
- Product Code
- Batch Number

Each component of Non Conventional System for Knee has electronically engraved in its body the following information:

- Name of the Company
- Batch Number
- Code

Storage:

A dry and airy place, far from direct sunlight, is recommended for storage.

Maintain the implant in its original package up to the moment of its use, under the responsibility of the doctor/hospital team nominated for that purposed.

Avoid beats and falls on hard surfaces to avoid damages to the product.

Do not store the product directly on the ground (minimum height = 20 cm).

Product cannot be stored in high shelves, next to light fixture (for not to became excessively dry or have the label information faded). Do not store product in areas where contaminating substances are used, like insecticides, pesticides or cleaning material.

Transportation:

Transport product with care, avoiding fall and friction, so that no damage is made to its surface. The integrity of the package has to be always observed.

Date of manufacturing, due date and batch number: see product label.

Further Information

Manufactured and distributed by:
MDT – Indústria Comércio Importação e Exportação de Implantes SA
Address: Av. Brasil, nº. 2983 – Distrito Industrial – Rio Claro/SP – Brasil
CEP: 13505-600
Phone/ Fax: (55-19) 2111-6500
CNPJ: 01.025.974/0001-92
Technician Responsible: Miguel Lopes Monte Júnior – CREA 0601150192

ANVISA Registration Nº: 10417940060
Review: 00
Issue: September 26th, 2005.

ALERT
INSTRUCTIONS FOR USE

These INSTRUCTIONS FOR USE are not available in printed form, they are available at the website of the manufacturer www.mdt.com.br.

The INSTRUCTIONS FOR USE on the website are indexed by REGISTRATION/ CADASTRE ANVISA´s NUMBER and its TRADE NAME of the product, informed at the label of the product purchased.

All the INSTRUCTIONS FOR USE provided on the website have the identification of the revision and date of emission of the document. The user must pay attention to the correct version (revision and date of emission) of the document regarding the MANUFACTURING DATE informed at the label of the product purchased.

If it is interest to the user, the INSTRUCTIONS FOR USE may be provided in printed form, with no extra cost and the request of the same shall be held by the SAC (Customer Service Department) manufacturer, as following:

Customer Service Department:
Telephone: +55 19 2111.6500
FAX: +55 19 2111.6500
http://www.mdt.com.br
Avenida Brasil, 2983 – Distrito Industrial CEP: 13505-600 | Rio Claro – São Paulo – Brasil

Opening Hours: 8 AM to 5 PM, from Monday to Friday, except holidays.

MDTImplantes

MDT®- INDÚSTRIA COMÉRCIO IMPORT. E EXPORT. DE IMPLANTES SA
Av. Brasil, 2983 - Dt. Industrial | 13505-600 - Rio Claro / SP - Brasil
Tel./Fax. +55 (19) 2111.6500 | www.mdt.com.br

SURGICAL TECHNIQUE

Standard Procedure

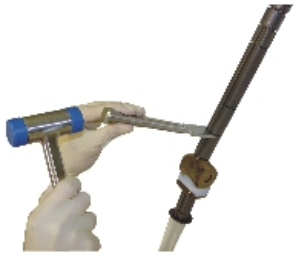
Impaction Base with intramedular stem module

Simulation of osteotomy regularization with the employment of proper device

Detail of regularization of the special device for osteotomy after introduction of the guide

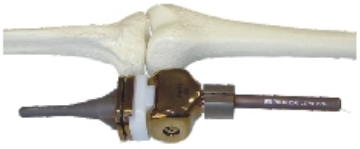
Milling simulation over guide

Exhibition of the opening made by milling



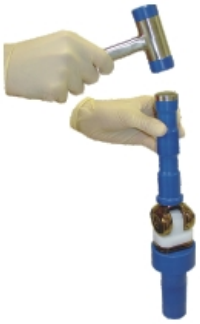
Device for disjointing of the modules

TECHNIQUES FOR KNEE



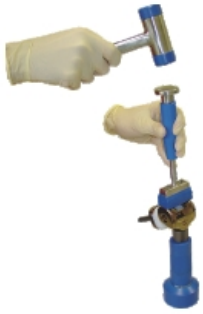
Knee Endoprothesis

Impaction of knee endoprothesis on the tibial base using proper polyethylene hammer



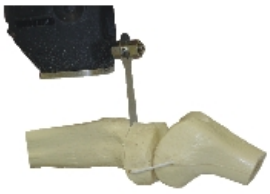
Impaction of knee endoprothesis on the tibial base using proper polyethylene hammer

Insertion of the knee module to the stem intramedullary module through "Morse" cone system with universal anti-rotating new jagged device



Impaction of "Morse" cone system applying proper hammer

Detail of the impaction



Preparation for placement of the tibia proximal component in the knee endoprothesis

Knee endoprothesis illustrating a parched knee

Aspect of the surface of proximal tibia with hole for introduction of wire guide

New instrumental for preparation of the proximal tibia: manual milling cutter, proper devices for preparation of the proximal tibia

Placement of preparatory guide for introduction of the manual milling cutter

Detail of the guide for introduction of the milling cutter

Introduction of milling cutter for proximal tibia

After removal of the internal guide, the manual milling cutter is deepened up to the groove shown in the detail

Milling of lateral furrows of proximal tibia. Aspect of the proximal tibia after preparation.

Device for removal of the preparation guide of the proximal tibia

Endoprothesis Impaction in proximal tibia with employment of polyethylene devices after cementation of the channel

Aspect of the endoprothesis after placement of the tibial proximal component

Final aspect of the endoprothesis sharpened resection model

General Aspect