Instructions for Use

Non-conventional System for Hip

Legend of the Symbols used in the Packages

REF	Catalogue Number	LOT	Batch Code
STERILE R	Sterile Product - Sterilized by Gamma Radiation	CE XXXX	Product certified in accordance with Directive 93/42/EEC). When applicable.
	Date of Manufacture		Valid until
	Consult instructions for use		Single-Use Product
	Do not use if package is damaged		Do not re-sterilize
	Keep out of the sun		Fragile, handle with care.
	Keep Dry		Temperature Limit (40°C);

Description

The Non-Conventional System for Hip is composed by modules of several sizes and formats, manufactured in titanium alloy according to ASTM F136 the technical specification, with the purpose of substituting articulations and the bony parts, mainly the ones affected by tumors.

It is a modular system and its components present a variety of sizes that allow the assembly of configurations more adapted to the treatment of the fracture.

Composition

The components of the Non Conventional System for Hip are manufactured in Titanium alloy, to attend to the requirements of the specification rule ASTM F136 - Specifications for Wrought Titanium Alloy -6 Aluminium-4 Vanadium ELI (Extra Low Extra Interstitial) R56401 for use in surgical implantation.(Standard Specification for Wrought Titanium-6 Aluminum -4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications).

Purpose

The purpose of the Non Conventional System for Hip is to substitute the articulation and bony parts of the Hip, mainly affected by tumors.

Incorrect selection, placement, positioning and fixation of the implant can cause undesirable results. The surgeon should be familiar with the material, the method of application and the surgical procedure prior to performing the surgery.

The system should not be used case there is no good bony support to assure the stability implants stability. In these circumstances, supplementary methods of bony grafting are to 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 implant, 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.

Note: The products described herein were developed for use under the circumstances described above, so that any other uses are considered contraindicated or without scientific substrate supporting its use.

Contraindications

The Non-Conventional System for Hip is contraindicated to the following patients:

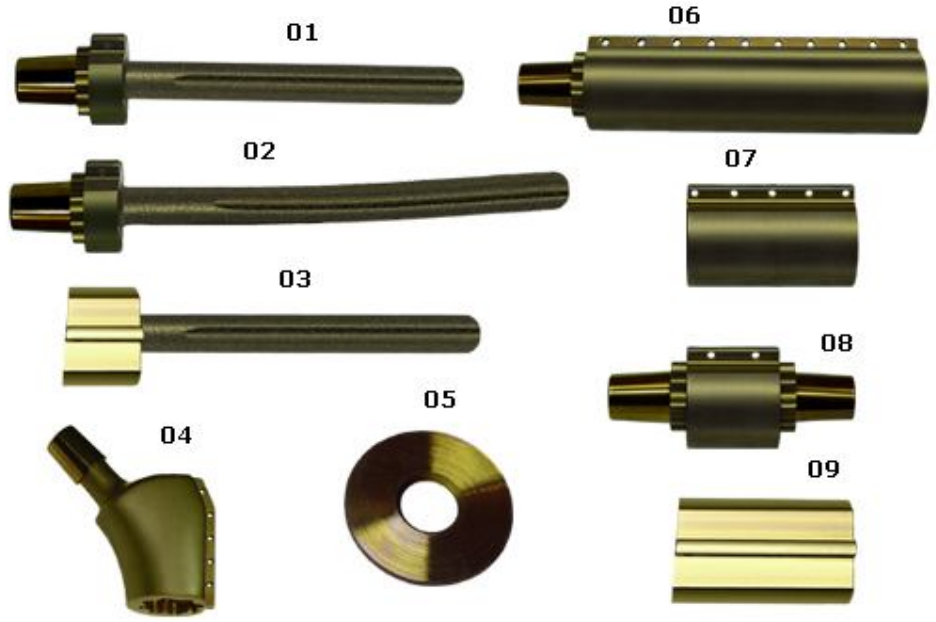
- Young or sports activities performers

- Patients weighing above 102 kilos
- Patients presenting infectious pathology, previous or present
- Patients presenting dementia
- Patients presenting sensibility to strange bodies
- Bony poor 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.

Forms of Presentation:

The Non Conventional System for Hip is composed of the following items:



The components that comprise the Non Conventional System for Hip are packaged unitary system in primary packaging Blister type system, sealed with surgical grade paper (Tyvec® type) or in surgical wrapping system Tyvec® type, which act as a barrier to sterilization. The product is available for commercialization in sterile condition, and the adopted sterilization method is sterilization by gamma radiation (dose 25 kGy), procedure performed by suitably qualified outsourced company.

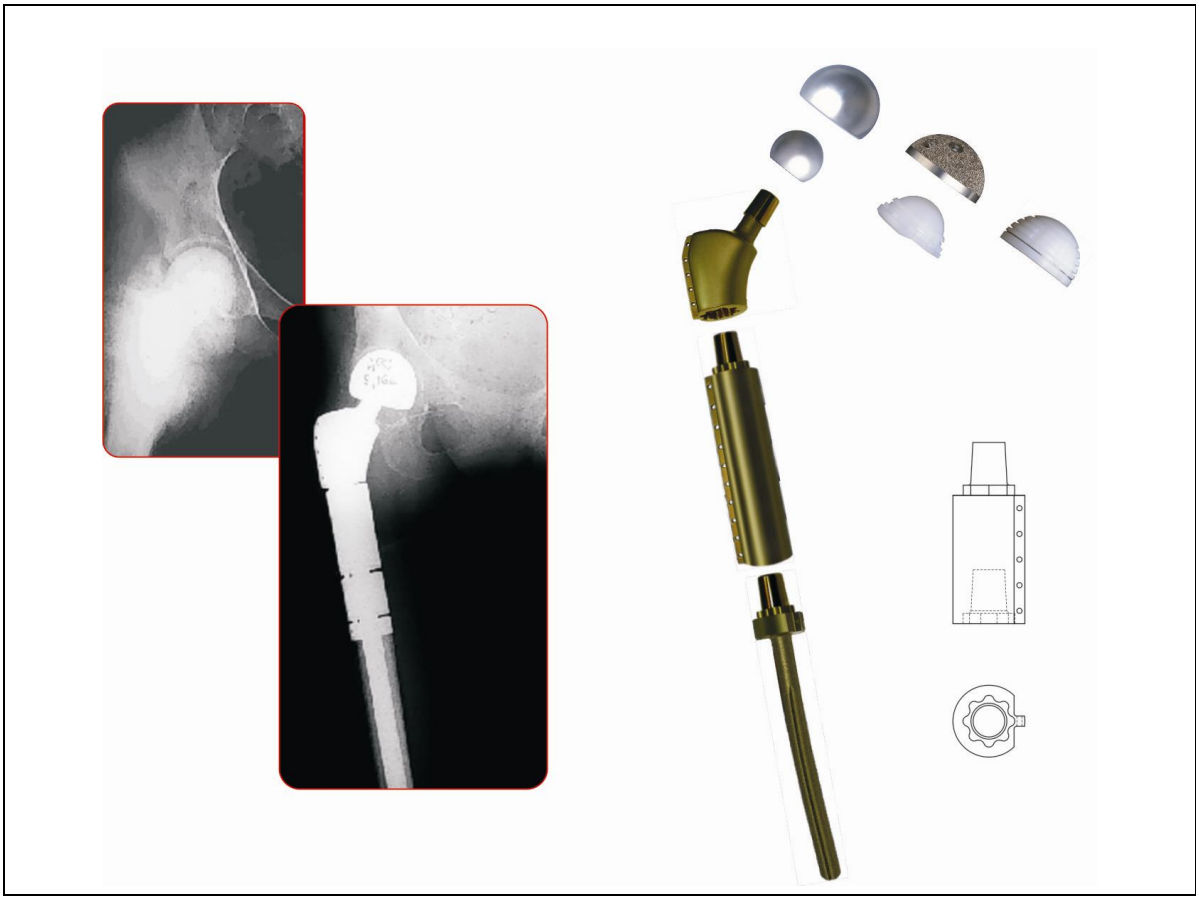
Once sterilized, the components packaged in their primary packaging properly labeled, are packed in cardboard cartons (secondary packaging), which contains five copies of the traceability label and a leaflet containing the instructions for the correct use and product handling.

On each primary packaging and on each carton is pasted a label containing the information needed to identify the product.

Description

Code	Description
04.07.46.00000	Endoprothesis Modular IOT Trochanteric Component Cone 12/14 Ti
04.07.40.08045	Endoprothesis Modular IOT Stem Cone 12/14 Ti 8 x 45 mm
04.07.40.08070	Endoprothesis Modular IOT Stem Cone 12/14 Ti 8 x 70 mm
04.07.40.08095	Endoprothesis Modular IOT Stem Cone 12/14 Ti 8 x 95 mm
04.07.40.09045	Endoprothesis Modular IOT Stem Cone 12/14 Ti 9 x 45 mm
04.07.40.09070	Endoprothesis Modular IOT Stem Cone 12/14 Ti 9 x 70 mm
04.07.40.09095	Endoprothesis Modular IOT Stem Cone 12/14 Ti 9 x 95 mm
04.07.40.10045	Endoprothesis Modular IOT Stem Cone 12/14 Ti 10 x 45 mm
04.07.40.10070	Endoprothesis Modular IOT Stem Cone 12/14 Ti 10 x 70 mm
04.07.40.10095	Endoprothesis Modular IOT Stem Cone 12/14 Ti 10 x 95 mm
04.07.40.11095	Endoprothesis Modular IOT Stem Cone 12/14 Ti 11 x 95 mm
04.07.40.11130	Endoprothesis Modular IOT Stem Cone 2/14 Ti 11 x 130 mm
04.07.40.11160	Endoprótese Modular IOT Haste Cone 12/14 Ti 11 x 160 mm
04.07.40.12095	Endoprothesis Modular IOT Stem Cone 12/14 Ti 12 x 95 mm
04.07.40.12130	Endoprothesis Modular IOT Stem Cone 12/14 Ti 12 x 130 mm
04.07.40.12160	Endoprothesis Modular IOT Stem Cone 12/14 Ti 12 x 160 mm
04.07.40.12180	Endoprothesis Modular IOT Stem Cone 12/14 Ti 12 x 180 mm
04.07.40.12200	Endoprothesis Modular IOT Stem Cone 12/14 Ti 12 x 200 mm
04.07.40.12250	Endoprothesis Modular IOT Stem Cone 12/14 Ti 12 x 250 mm
04.07.40.14095	Endoprothesis Modular IOT Stem Cone 12/14 Ti 14 x 95 mm
04.07.40.14130	Endoprothesis Modular IOT Stem Cone 12/14 Ti 14 x 130 mm
04.07.40.14160	Endoprothesis Modular IOT Stem Cone 12/14 Ti 14 x 160 mm
04.07.40.14180	Endoprothesis Modular IOT Stem Cone 12/14 Ti 14 x 180 mm
04.07.40.14200	Endoprothesis Modular IOT Stem Cone 12/14 Ti 14 x 200 mm
04.07.40.14250	Endoprothesis Modular IOT Stem Cone 12/14 Ti 14 x 250 mm
04.07.52.11130	Endoprothesis Modular IOT Stem Fem. c/ Anti-curvato Cone 12/14 Ti 11x 130mm
04.07.52.12130	Endoprothesis Modular IOT Stem Fem.c/ Anti-curvato Cone 12/14 Ti 12x 130 mm
04.07.52.13130	Endoprothesis Modular IOT Stem Fem.c/ Anti-curvato Cone 12/14 Ti 13x 130 mm
04.07.52.14130	Endoprothesis Modular IOT Stem Fem.c/ Anti-curvato Cone 12/14 Ti 14x 130 mm
04.07.42.12095	Endoprothesis Modular IOT Stem Right/Left Cone 12/14 Ti 12 x 95 mm
04.07.43.00000	Endoprothesis Modular IOT Tibial Base Cone 12/14 Ti
04.07.43.00001	Endoprothesis Modular IOT 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	Endoprothesis Modular IOT Intermediary Componente Cone 12/14 Ti 25 mm
04.07.44.00050	Endoprothesis Modular IOT Intermediary Componente Cone 12/14 Ti 50 mm
04.07.44.00100	Endoprothesis Modular IOT Intermediary Componente Cone 12/14 Ti 100 mm
04.07.47.00045	Endoprothesis Modular IOT Diaphisary Internal Cone 12/14 Ti 45 mm
04.07.48.00025	Endoprothesis Modular IOT Diaphisary External Cone 12/14 Ti 25 mm
04.07.49.00048	Endoprothesis Modular IOT Comp. Angular Right/Left Cone 12/14 Ti 48 mm

Demonstration of the forms of implantation of the system:



Data and features of instruments and ancillary:

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

The Instrumental Kit for application of the Non Conventional System for Hip is registered at Anvisa.

Contact MDT representative to obtain more information reference the Instrumental.

The Instrumental Kit for application of Non Conventional System for Hip is composed of the following items:

Description
Wire Guide
Final Impactor
Module Extractor
Head Tester
Intramedular Tibial Drill Guide
Diaphisary Milling Cutter
Stem Impactor
Tibial Channel Moulder
Hammer
Base for Impactor
Flexible Drill

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:

- Product Code
- Batch Number
- Company Logotype

Precautions

- Non-Conventional System for Hip 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.
- Osseous necrosis induced by irradiation in consequence of radiotherapy due to cancer treatment is contraindication, 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.
- **SINGLE USE PRODUCT – DO NOT REUSE;**
- **Non-Conventional System for Hip is supplied sterile.**
- Sterile Product – Do Not Re-Sterilize;
- Discard and DO NOT USE open or damaged devices. Use only devices properly packed in shut and not damaged packages.
- 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 Hip 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.
- Discard and do not use previously opened or damaged devices. Use only devices that are packaged in unopened and undamaged packages.

Adverse Effects

In addition to the fact that obvious risks can occur in the presence of orthopedic implants, like failure, loosening and breakage, 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 necrosis or soft tissues
- 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.

The patient should also be informed that any circumstances that take to tissular chronic injury can be oncogenic. Cancerous tissue found next to implants can be related to factors not linked directly to the implant itself, such as: primary lung tumor metastasis, breast, digestive system and other, or also due to implantation of cancerous cellules which can happen during surgical procedures or diagnostics like biopsy, or still, resulting from progression of the Paget´s disease.

The implantation of strange material to organic tissues can result in inflammatory reactions, which can happen, for example, in the presence of debris arose from implant (like metallic debris 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

- All the restrictions after surgery, mainly the ones related to sports and occupational activities.
- The fact that complications or failures arisen from the total arthroplasty of the hip are much common to occur in:
  - patients with functional expectations beyond the ones offered by the articular substitution;
  - patients with high corporeal weight, especially above 102 kilos;
  - young and/or dynamic patients;
  - patients with small ossature;
- The complications related to hip total arthroplasty, listed in the topic Adverse Effects and the information listed in the topics: Indications, Contraindications, Precautions and Warnings.
- 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 or osteolysis femoral, 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 an 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.;

Warnings

- 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 Hip exclusively in proper environment (ambulatory or surgical room), taking adequate manipulation care (use of sterilized gloves). Only qualified professionals should manipulate and implant the Non-Conventional System for Hip.

Non-Conventional System for Hip should be 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 Hip together with products of other brands, because there can be incompatibility problems among the materials.

Sterilization

The Non-Conventional System for Hip is available in sterile condition. It is adopted the Gamma Radiation (dosage of 25 kGy) Sterilization method.

The product manufacturing process is done with great care, in order to meet the intended performance for it. So, the surgical team and all the other who are involved with the procedure should handle the devices properly in order to minimize the infection risks.

Sterile Product – Do Not Re-sterilize.

Do Not use the product if the package is violated.

Contamination Risk

Considering that the implantable components enter into contact with tissue and corporal fluids, there is the risk of biological contamination and transmission of infectious 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.

The pieces removed from patients must be discarded. **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 its reuse.

To discard the removed components of Non Conventional System for Hip, follow the legal procedures for discarding of products potentially contaminants, in force in the country where the material will be discarded.

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

The Components of the Non Conventional System for Hip has printed in its body the following information:

- Name of the Company
- Batch Number
- Product 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.
- Once it is a sterile product, the humidity and temperature of the storage site should be monitored, and the temperature should be kept below 40 º.

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.

Engineer Technical Responsible: Miguel Lopes Monte Júnior – CREA 0601150192

Anvisa registration Nº: 10417940063

Revision: 01

Issue: May 13Th, 2013.

Manufactured and distributed by:

MDT Indústria Comércio Importação e Exportação de Implantes SA
Avenida Brasil, nº 2983 – Distrito Industrial – Rio Claro/SP – Brasil
CEP 13.505-600
CNPJ: 01.025.974 / 0001-92
Atendimento ao consumidor: (55-19) 2111-6500
www.mdt.com.br

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 CAP (Customer Service Department) manufacturer, as following:

Customer Service Department – CAP:

Telephone: +55 19 2111.6500

FAX: +55 19 2111.6500

http://www.mdt.com.br/contato

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.

SURGICAL TECHNIQUE

Procedimentos Padrões

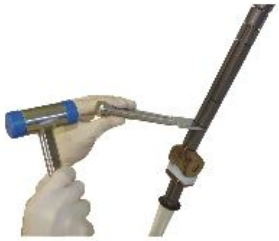
Base de impacção
com módulo da haste
intra-medular

Simulação de regularização
de osteotomia com
emprego de dispositivo próprio

Detalhe de dispositivo
especial de regularização
de osteotomia após
introdução do guia

Simulação de fresagem
sobre guia

Mostra de abertura
pela fresagem



Dispositivo para desencaixe
dos módulos

Técnicas para Fêmur

Impacção do módulo de fêmur proximal sobre módulo de 100mm e da haste intramedular

Impacção do módulo de haste intramedular com batedor próprio de polietileno

Endoprótese de fêmur proximal

Introdução da haste intramedular com centralizador

Endoprótese de fêmur proximal colocada no canal femoral

Técnicas para Fêmur Total

Endoprótese com 2 módulos intermediários de 50mm no fêmur e 1 na tíbia

Endoprótese de fêmur total com componente de 50mm na tíbia

Vista Ampliada