Instructions for Use

Shoulder Prosthesis

Symbols used in the Packaging

REF		Product Code		Avoid exposure direct to sunlight
LOT		Batch Number		Keep protected of Humidity
		Read the Use Instructions		Caution - Fragile
Materials **Ss** and **UHMWPE**		Stainless Steel Alloy (ASTM F138) and Polyethylene - UHMWPE (NBR ISO 5834-2)		
DD/MM/YYYY		Manufacturing Date		Do not Re-sterilize
		Do not use if the packaging is violated		Single Use Product
Sterile	**R**	Sterilized by Gamma Radiation		

Description:

The Shoulder Prosthesis consists of a humeral intramedullary stem, an interchangeable head and a glenoid component. The humeral stem and interchangeable head are manufactured from stainless steel and the glenoid component is made from polyethylene.

The Shoulder Prosthesis is supplied in the sterile condition.

The humeral intramedullary stem has anatomical profile that is inserted and fixed in the humerus medullary canal, through bone cement.

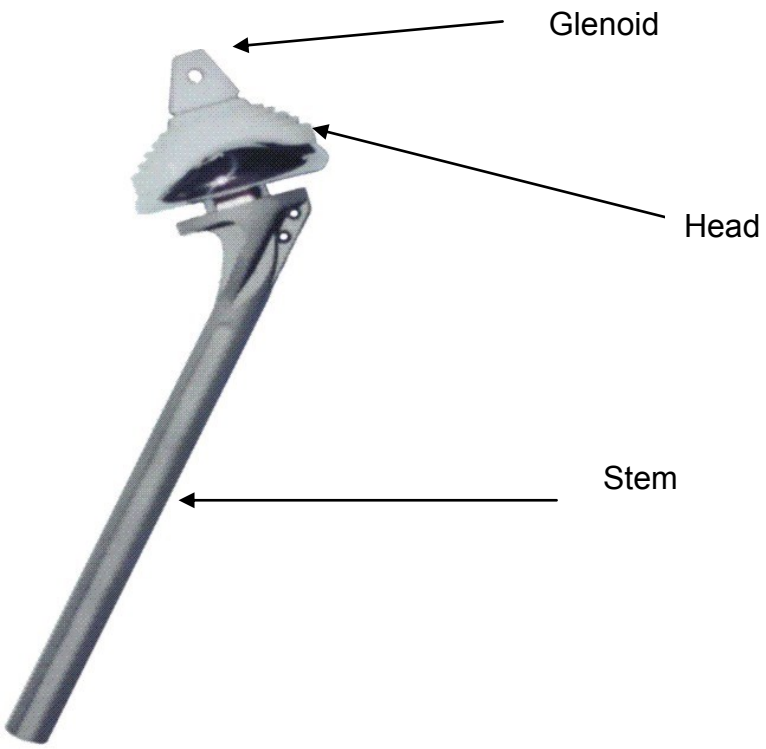
In the region lateral / medial proximal of the stem there are three fins in “V”, with the purpose to avoid rotational movements and to fix bone fragments from fractures.

In the region proximal, the prosthesis has a cone Morse characteristic of modular prosthesis that is intended to accommodate a humeral head, for articulation with the glenoid cavity (scapula) in partial surgeries or to articulate with the glenoid component, when is a total arthroplasty of shoulder.

The interchangeable head is a means of joint between the humeral component and the glenoid. The external region is a surface semi-spherical and has the purpose, to articulate with the natural glenoid cavity (partial surgeries) or the glenoid prosthetic component (total surgeries). In the internal region there is a cone Morse intended to connect with the humeral stem.

The glenoid component is an anatomical prosthetic component with the purpose to articulate with the humeral head, in total arthroplasty of shoulder.

The internal surface of this component is concave and allows perfect joint with the humeral head, while the external surface has a small triangular stem (grooved) that is fixed in the natural glenoid cavity (scapula), through bone cement.



Composition

The humeral stem and the interchangeable head are produced from stainless steel, as the specification ASTM F138 - Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants.

The glenoid component is manufactured from Polyethylene (UHMWPE) that meets the standard NBR ISO 5834-2.

Purpose:

Replace totally the Shoulder joint.

The use of the shoulder prosthesis is indicated for treatments with intense pains or cases of degenerative disease or traumatic arthritis of the glenohumeral joint, fractures not united in the long term of the humeral head; irreducible fracture of the proximal extremity of the humerus; avascular necrosis of the humeral head or other clinical difficulties where the arthrodesis or arthroplasty resectional are not acceptable.

Important Note: The products described here were developed for use in the circumstances above, so that any other uses are considered contraindicated or without scientific substrate that supports its use.

CONTRA-INDICATION

The shoulder prosthesis must not be used if there is no proper bone support to ensure the implant stability. In these circumstances, supplementary methods of bone grafting must be used together, with autologous or homologous grafting. In this last case, it is necessary to ensure support of a least 50% of the circumference of the implant in the patient's own bone.

The bone necrosis induced by irradiation in consequence of radiotherapy for cancer treatment is contraindication relative to replacing articular of the shoulder, since the lack of glenoid bone support can lead to the early loosening of the implant. In these cases other techniques and system of implants must be used.

The reconstruction of the shoulder is contraindicated for:

- Patients young or that practice sportive activities;
- Patients with overweight, above 102 kilograms;
- Patients with prior or current infectious pathology;
- Patients with dementia or neurologic changes of lower limbs.

The use in the above cases may cause wear or early loosening of the glenoid component by excessive mechanical stress, infections and prosthetic luxation.

Presentation of available measures

The Shoulder Prosthesis is available in the following presentations:

Humeral Intramedullary Stem

Code	Description
04.29.01.07130	Stem Ø 7 x 130 mm
04.29.01.08130	Stem Ø 8 x 130 mm
04.29.01.10130	Stem Ø 10 x 130 mm
04.29.01.11130	Stem Ø 11 x 130 mm
04.29.01.13130	Stem Ø 13 x 130 mm

Interchangeable Head

Code	Description
04.04.05.14034	Head Ø 34 mm
04.04.05.14038	Head Ø 38 mm
04.04.05.16040	Head Ø 40 mm
04.04.05.20044	Head Ø 44 mm

Glenoid Component

Code	Description
04.29.01.00001	Glenoid - Pe

The selection criteria of type and size of the shoulder prosthesis components to be used, depends on of the type of fracture, the bone conditions and size of the patient. These conditions are responsibility of the doctor that assesses the patient and decide which materials to use.

Incorrect selection, placement, positioning and fixation of the implants may cause undesirable results. The surgeon must be familiar with the material, the method of application and surgical procedure before surgery.

The shoulder prosthesis must not be used if there is no proper bone support to ensure the implant stability. In these circumstances, supplementary methods of bone grafting must be used together with autologous or homologous grafting, or yet with help of mesh and accessories.

IMPORTANT:

For deployment of the Shoulder Prosthesis is need the use of specific instrumental, which must be acquired separately of the Shoulder Prosthesis.

The Instrumental Kit for Application of Shoulder is registered in the Anvisa.

The Instrumental Kit for Application of Shoulder is composed of the following items:

Description
Impactor of Humeral Prosthesis
Impactor of Glenoid
Retractor
Retractor Hook Humeral
Retractor Humeral Small
Retractor Humeral Large
Retractor Glenoid Small
Retractor Glenoid Large
Retractor Anterior Glenoid Small
Retractor Anterior Glenoid Large
Retractor Afastador Deltoid Small
Retractor Deltoid Large
Reamer Humeral
Proof of Prosthesis Small
Proof of Prosthesis Large

The surgical instrumentals are subject to wear and tear during the normal use, and it can therefore break. The surgical instruments must be used only for its purpose and must be inspected regularly to check possible wear and damages.

The surgical instruments must be purchased separately and always from the same manufacturer of the implant.

The instrumentals are provided decontaminated, but not sterilized. They receive engraving of:

- Product Code;
- Batch Number;

- Logotype of the Company;

ADVERSE EFFECTS

In addition to the fact that obvious risks can happen at presence of orthopedic implants, as the failure, loosening and fracture, the risks of adverse tissue answers and complications possible must be presented and discussed with the patient:

Though no scientifically proven association between the use of orthopedic implants with the same characteristics of materials as the used in this type of implant and the occurrence of cancer, any risks and the uncertainty about the long-term effects of joint replacements, must be discussed with the patient before surgery. The patient must also be informed that any circumstances that may lead to chronic tissue damage can be oncogene.

Cancerous tissues found in the implant vicinity may be related to factors not linked directly to the implant such as: metastases from primary lung tumors, breast, digestive system and others, or yet due to implantation of cancerous cells that may occur during operatory procedures or diagnoses such as biopsy or yet resulting from progression of the Paget illness;

The implantation of foreign materials in organic tissues may elicit inflammatory responses that can happen, for example, at presence of debris from implants (as metallic debris or polyethylene), which can cause response histiocytic type strange body granuloma, thus causing bone destruction, associated or not at implant loosening;

Sensibility or atopic to metal can be found after the implantation of orthopedic devices, as for example, which occurs with Nickel, cobalt and chrome that are presents in the steel stainless alloy of orthopedic implants.

PRECAUTIONS

- **SINGLE USE PRODUCT – DO NOT REUSE;**
- **The Shoulder Prosthesis is supplied sterile;**
- Use immediately after opening the sterilization seal;
- Discard and DO NOT USE opened or damaged devices. Use only devices that are packed in sealed and undamaged;
- **DO NOT** USE in case of loss of sterility;
- **DO NO RE-STERILIZE;**
- It is not recommended the use together with implantable components of other manufacturers, due to the incongruence between the head and the implant cavity;
- It is recommended the use of antibioticterapy prophylactic in patients carrying of joint replacements or undergoes procedures that cause transitory bacteremy (dental procedures, endoscopy, catheterization of large vessels in the groin and other minor surgical procedures);
- The Shoulder Prosthesis was designed to be implanted with the use of instrumental, specially developed for this purpose. The kit for application of the shoulder prosthesis presents the

necessary instrumentals for proper insertion and positioning of the implant. Any improvisations with different instrumentals or inaccurate surgical technique may compromise the quality of fixation and/or positioning of the implant;

- In some occasions reinforcements in the form of bone grafting or devices of containment and support, may be indicated to restore the bone stock and to ensure a good stability of the implant;
- To implant the component in improper bone bed may result in premature loosening, loss of bone stock and metallosis.

THE PATIENT MUST BE INFORMED ABOUT:

A. All the postoperative restrictions, especially those related to sports and occupational activities;
B. The fact that complications or failures are more likely to occur in:
   - Patients with functional expectative beyond what can be promoted by the joint replacement;
   - Patients with overweight, above 102 kilograms;
   - Patients young and/or actives;
   - Patients with small bones.
C. The information listed in topics: **Indications**, **Contra Indications**, **Adverse Effects**, **and Precautions and Warnings**;
D. The need of periodic medical monitoring to observe possible changing in the implant condition and adjacent bone. The lack of monitoring prevents the release of components or the occurrence of osteolysis;
E. The non-performing of the review' surgery when the components loosen and femoral osteolysis occurs, can result in progressive loss of periprosthetic bone stock;
F. The need to inform, when is performing magnetic resonance examination, about the fact of being a metallic prosthesis user;
G. Must alert the patient and make him understand that the product does not substitute and does not have the same performance of the normal bone and therefore can break, deform or loosen, due to excessive effort or activities of early load, etc.;

Warnings:

1. DISCARD AND DO NOT USE OPENED OR DAMAGED DEVICES. USE ONLY DEVICES THAT ARE PACKED IN SEALED AND UNDAMAGED;
2. THE CARE WITH THIS MATERIAL IS THE RESPONSIBILITY OF QUALIFIED PERSONNEL;
3. THE PATIENT MUST BE PERIODIC MEDICAL MONITORING TO CHECK THE CONDITIONS OF THE IMPLANT AND BONES;
4. IMPROPER STERILIZATION OF SURGICAL INSTRUMENTAL CAN CAUSE PROSTHETIC INFECCTION;
5. THE PRODUCT IDENTIFICATION MUST BE STRICTLY OBSERVED AND MIXTURES WITH IMPLANTS AND/OR INSTRUMENTALS FROM OTHER ORIGIN OR PURPOSE CAN NOT BE ALLOWED;
6. THE CLINICAL RESULTS AND DURABILITY OF THE IMPLANTS ARE STRICTLY DEPENDENTS ON AN ACCURATE SURGICAL TECHNIQUE;

7. THE RESISTANCE LIMIT OF THE IMPLANT MUST BE RESPECTED, WHICH VARIES ACCORDING TO TYPE, UNDER RISK OF WEAKENING AND POSSIBLE FRACTURE OF THE MATERIAL;
8. SINGLE USE MEDICAL PRODUCT – DESTROY AFTER EXPLANTATION;
9. NEVER REUSE AN IMPLANT, ALTHOUGH WITHOUT EXTERNAL APPEARANCE OF DAMAGE, PREVIOUS EFFORTS MAY REDUCE ITS USEFUL LIFE;

Use Instructions

The surgery techniques vary according to the surgeon choice. He is responsible by the final method, type and dimension of the products to be used, as well as the criterion for evaluation of the surgery results.

- Handle the Shoulder Prosthesis exclusively in proper environment (ambulatory or surgical room), with proper care (must only be handled with sterile gloves). Only qualified professionals must handle and implant the Shoulder Prosthesis.
- The Shoulder Prosthesis must be applied and adapted according to requirements and proper surgical techniques.

The clinical results and the durability of the implants are extremely dependent of the tridimensional alignment of the components, being, therefore, essential to apply a precise surgical technique;

The use of different alloys in the metallic junctions may cause galvanic corrosion of the implant;

Do not use the Shoulder Prosthesis together with products of other brands, due to problems of incompatibility between materials.

Contamination Risk

Considering that the Shoulder Prosthesis enters into contact with tissue and corporal fluids, there is the risk of biological contamination and transmission of viral diseases such as Hepatitis and HIV etc. Therefore, removed Shoulder Prosthesis must be treated as potentially contaminant materials.

Discard of Product

Falls or crushing over hard surfaces can cause damage to the product. The product integrity must be inspected when opening the package. Do not use the product if any abnormality is observed.

After been removed from the patient, discard all implants. **They should not be reused**.

The implants removed or defective due to accidents must be destroyed before being discarded. We recommend that the parts are cut, bent or filed for its destruction.

To discard the removed Shoulder Prosthesis, follow the legal procedures for discarding of products potentially contaminants.

Traceability

For ensuring the traceability of the implanted product and fulfill the Sanitary Authority requirements, we recommend that the surgeon responsible by the implant, report to the Distributor the following information related to the implanted product, patient and surgery:

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

Each component of Shoulder Prosthesis has engraved in its body, the following information:

- Measure
- Code
- Logotype of the Company
- Manufacturing Batch

STORAGE AND TRANSPORT:

In the transport and storage must be observed the following conditions:

- the parts must not be thrown and beaten;
- Must not be placed excessive weight over the parts.

The storage area must be protected from direct light to preserve the packaging and labeling, and free of moisture and contaminants.

Always keep the implants in their original packaging until the moment of use, under the responsibility of the medical/hospital team designated for this purpose.

Manufacturing date, expiry date and batch number: see 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: 10417940056
Review: 00
Issue: August 29th, 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:

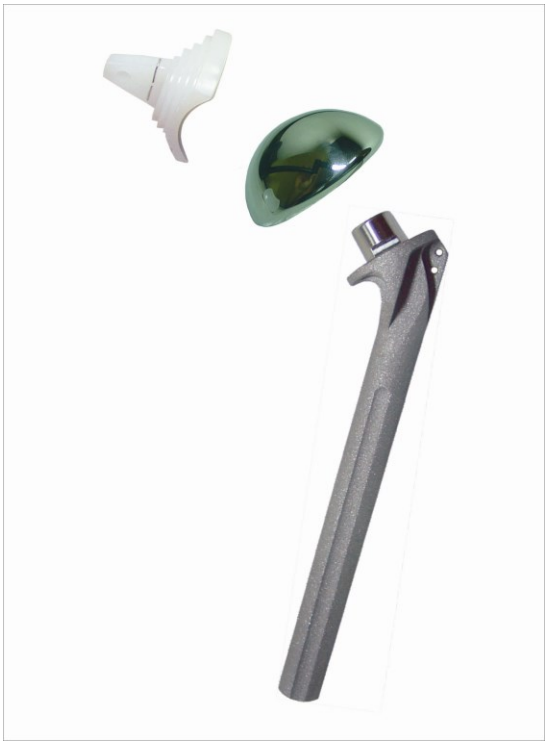
Customer Service Department:
Telephone: +55 19 2111.6500
FAX: +55 19 2111.6500
http://www.mdt.com.br
Avenida Brasil, 2983 – Distrito Industrial CEP: 13505-600 | Rio Claro – São Paulo – Brasil

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

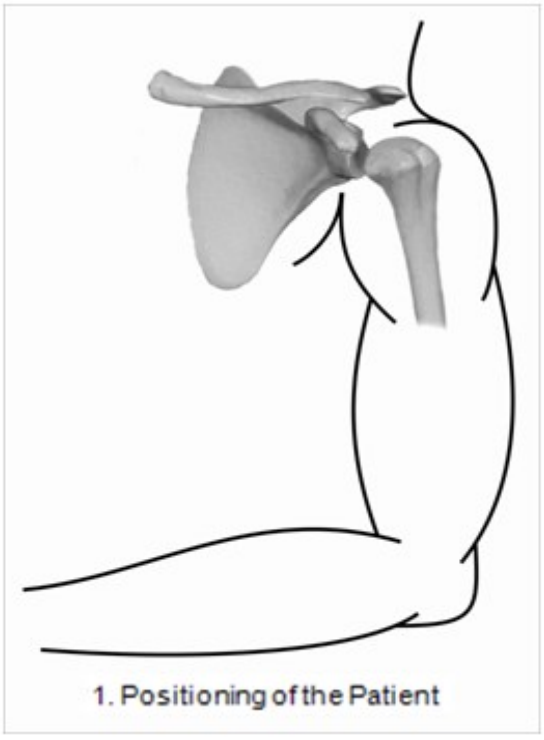
MDTImplantes

SURGICAL TECHNIQUE

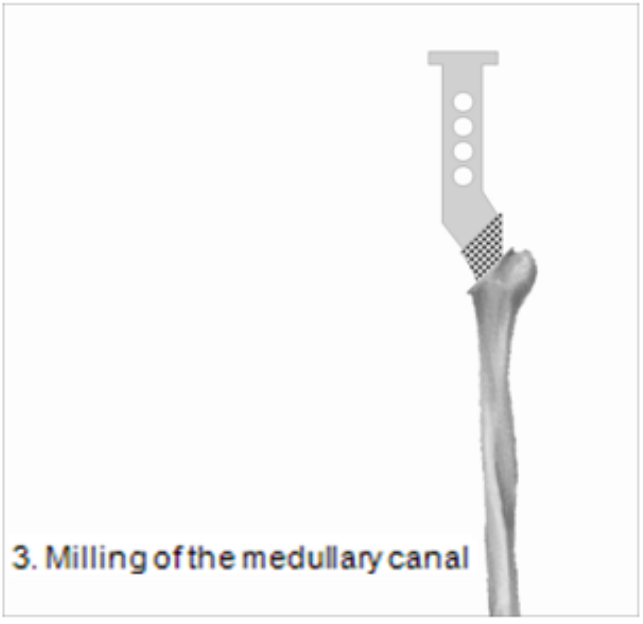
Shoulder Prosthesis



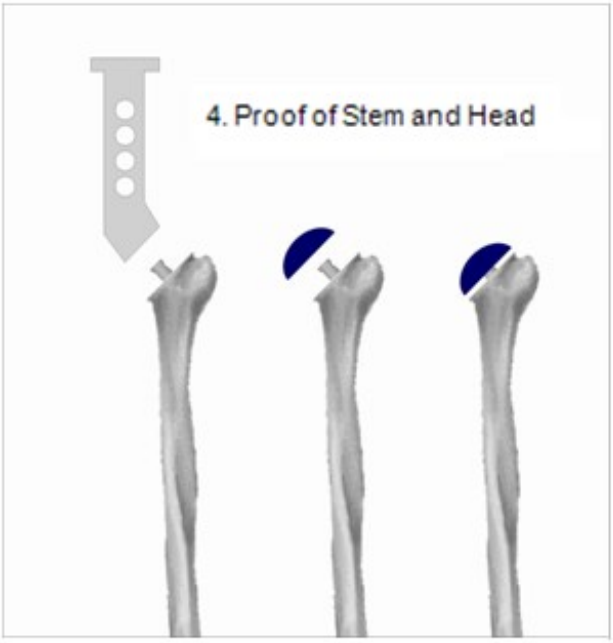
2. Osteotomy of the Humeral Head

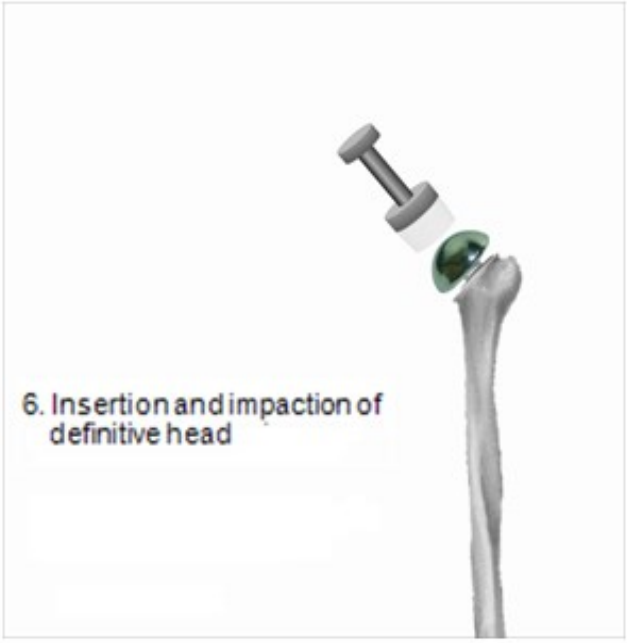


1. Positioning of the Patient



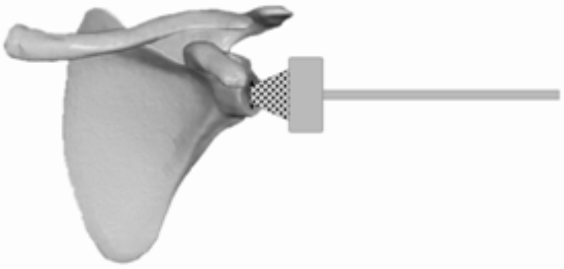
3. Milling of the medullary canal


4. Proof of Stem and Head


6. Insertion and impaction of definitive head

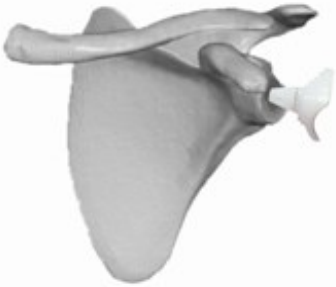

5. Introduction of the definitive prosthesis and confirmation of the diameter of the head


7. Preparation of scapula for introducing of the Glenoid



8. Milling of the scapula

10. Final reduction



9. Introduction of the Glenoid Component