Instructions for Use

Cemented Femoral Component

Legend of symbols used in the packages

REF		Product Code		Avoid direct exposition to sunlight
LOT		Batch Number		Protect from Humidity
		Read Use Instructions		Caution - Fragile
Material CrCo		ASTM F-75		Do not use if package is violated
DD/MM/YYYY		Date of Manufacturing		Expiration Date
Sterile	**R**	Sterilized by Gamma Radiation		Single use Product

Description

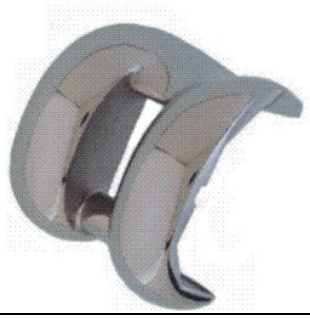
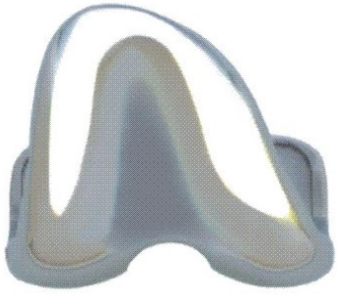
The Cemented Femoral Component is an implantable product, surgically invasive of long term use that composes the modular prosthesis used in surgeries of knee arthroplasty.

The implant is destined, together with the other components, to substitute the articular surface of the distal femur, proximal tibia and patellar surface during the surgical procedure of total articular substitution of knee, made in circumstances in that this articulation, in individuals skeletally mature, is affected in consequence of pathologies like non inflammatory articular degenerative disease (osteo-arthrosis), traumatic arthritis, ankylose of non infectious origin and knee arthrodesis.

The Femoral Component is endowed with a metallic extension that adjusts itself to the femoral channel in valgus angle of 9 degrees with the articular surface, in right and left sides, in the case of the Modular II revision system and in right and left side versions for Modular III primary and revision, and further with option for substitution with preservation of posterior cruciate ligament, Modular III/PL system.

The Cemented Femoral Component is manufactured from cast alloy of ASTM F-75 Chromium Cobalt and developed for surgical fixation to the adjacent bone by acrylic cement.

Following are illustrative images of the available models of Cemented Femoral Components:

		
Primary Femoral Component - Modular II	**Revision Femoral Component - Modular II**	**Primary Femoral Component - Modular III**

	
Revision Femoral Component – Modular III	**Primary Femoral Component - Modular III/PL**

The essential parts (accessories) of the Cemented Femoral Components are the femoral wedge and the stem extension; these parts are optionally used for cases in that the surgeon does not find a good bony bed for fixing the prosthesis. Also manufactured from casting alloy of Chromium Cobalt, the femoral wedge, as well as the stem extension is more commonly used in the revision cases, that is to say, in the cases in that it is necessary to change a femur primary component by one of revision.

Following are illustrative images of the accessories (essential parts):

Partial Femoral Wedge– Modular II

Total Femoral Wedge – Modular II

Stem Extension – Modular II

Anterior Femoral Wedge – Modular III

Posterior Femoral Wedge – Modular III

Femoral Distal Wedge– Modular III

Straight Stem Extension – Modular III

Angulate Stem Extension – Modular III

Composition

The Cemented Femoral Component, as well as its accessories – femoral wedge and stem extension – is produced from casting alloy of Chromium Cobalt. The choice for such alloy is based on similarity criterion (results widely described in the literature) and by its characteristics of biocompatibility and mechanical resistance.

The Chromium Cobalt alloy used to manufacture the Cemented Femoral Component and its accessories fulfills the requirements specified by rule ASTM F-75 – Specification for Cobalt-28 – Chromium-6 – Molybdenum for surgical implants (ASTM F-75 Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075).

The selection of such alloy is due to its well defined mechanical and metallurgical characteristics, as well as to the results in service – widely described in world-wide literature – that confirm that those alloys are biocompatible and possesses adequate mechanical resistance to the proposed purposes.

Indication and Purpose

The Femoral Component composes the system of knee total arthroplasty and is destined to substitute the articular surface of the distal Femur during the surgical procedure of total articular substitution of knee, put into practice in circumstances that this articulation, in individuals skeletally mature, is affected in consequence of pathologies like non inflammatory articular degenerative disease (osteo-arthrosis), traumatic arthritis, ankylose of non infectious origin, knee arthrodesis.

In any circumstances the Cemented Femoral Component should be fixed to the adjacent bone by using acrylic cement for orthopedic use (Polymethyl-metacrylate – PMMA).

Contraindications

Like any medical treatment, in general, all surgical technique even when well applied, can present problems, complications and situations where the final objective of the treatment is not partially or totally obtained, being its contraindication relevant, depending on each case, involving the anatomy, local and systemic biology and the precaution taken during planning and preparation before surgery, the performance and application of a perfect intra-operative technique and also the socio-economical and cultural profile, in the sense that the patient will co-operate and respect the recommendations to be followed after surgery.

Specific contraindications include: active infection be it in the place to be operated or in other regions, neuropathic articulation, absence or paresis of the musculature that controls the knee, progressive neurological disease, rapidly destructive bony diseases, or post irradiation osteonecrosis.

Relative contraindications include absence of good bony support to allow adequate fixation of the implant to the remaining bony. The system for cemented arthroplasty of knee should not be used in case there is no good bony support to assure the implant stability. In these circumstances, supplementary methods of bony grafting are to be used together, be it autologous or homologous graft, or yet, with the help of screens and accessories.

Bony necrosis induced by irradiation in consequence of radiotherapy due to cancer treatment is relative contraindication to knee articular substitution, once the lack of bony support can lead to premature loosening of the implant. In this case, other techniques and implant systems should be used.

Constitute also specific contraindications, neurological diseases that can bring alterations to bony resistance or neuromuscular activity that can overload the implant. Bony diseases rapidly destructive (for example: Charcot Arthropathy, bony tumors, etc), osteonecrosis, especially post-irradiation ones, may originate infection and dehiscence problems, local circulatory diseases, insufficiencies being arterial or veined, systemic diseases that due to reduction of local or general defenses or of circulatory condition may predispose to complications, and known or informed presence of any peculiar condition of the patient that can bring bio-incompatibility with the metallic alloy used in manufacturing of the implant.

The Cemented Femoral Component is also contraindicated to the following patients:

- Young or sports activities performers;
- With high corporal weight;
- With infectious pathology, previous or present;
- Presenting aspects of dementia or neurological alterations of the inferior members.

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

The products here described were developed to be used in the above described circumstances, so that any other kind of use is considered contraindicated or without any scientific substratum.

Forms of Presentation

The Cemented Femoral Component is presented in the following models, being each one of them, as well as their accessories (essential parts) available to be traded in the following dimensions:

Femoral Componente Modular II - Primary

Code	Description	Available Sizes
04.15.01.000XX	Femoral Component Modular II - Primary	54, 59, 64, 69 mm
04.15.02.000XX	Femoral Component Modular II Revision Right	54, 59, 64, 69 mm
04.15.03.000XX	Femoral Component Modular II Revision Left	54, 59, 64, 69 mm
04.15.04.000XX	Femoral Component Modular III Right – Primary	Small, Medium, Large & E. large
04.15.05.000XX	Femoral Component Modular III Left – Primary	Small, Medium, Large & E. large
04.15.08.000XX	Femoral Component Modular III Revision Right	Small, Medium, Large & E. large
04.15.09.000XX	Femoral Component Modular III Revision Left	Small, Medium, Large & E. large
04.15.06.000XX	Femoral Component Modular III - P/L Right	Small, Medium, Large & E. large
04.15.07.000XX	Femoral Component Modular III - P/L Left	Small, Medium, Large & E. large

Accessories – Femoral Wedge and Stem Extension - Modular II

Code	Description	Available Sizes
04.05.01.54XXX	Parcial Femoral Wedge 54	05 and 10 mm
04.05.01.59XXX	Parcial Femoral Wedge 59	05 and 10 mm
04.05.01.64XXX	Parcial Femoral Wedge 64	05 and 10 mm
04.05.01.69XXX	Parcial Femoral Wedge 69	05 and 10 mm
04.05.02.54XXX	Total Femoral Wedge 54	05 and 10 mm
04.05.02.59XXX	Total Femoral Wedge 59	05 and 10 mm
04.05.02.64XXX	Total Femoral Wedge 64	05 and 10 mm
04.05.02.69XXX	Total Femoral Wedge 69	05 and 10 mm
04.25.00.XX077	Stem Extension Ø 10 mm	Ø 10, 11, 12, 13, 14, 15 & 16 mm

Accessories – Femoral Wedge and Stem Extension – Modular III

Code	Description	Available Sizes
04.05.10.000XX	Femoral Wedge Modular III Anterior	Small, Medium, Large & E. large
04.05.11.050XX	Femoral Wedge Modular III Posterior - 5 mm	Small, Medium, Large & E. large
04.05.11.100XX	Femoral Wedge Modular III Posterior - 10 mm	Small, Medium, Large & E. large
04.05.12.050XX	Femoral Wedge Modular III Distal - 5 mm	Small, Medium, Large & E. large
04.05.12.100XX	Femoral Wedge Modular III Distal - 10 mm	Small, Medium, Large & E. large
04.25.02.XX070	Straight Stem Extension Modular III - 70 mm	Ø 09, 10, 11, 12, 13, 14, 15 mm
04.25.02.XX100	Straight Stem Extension Modular III - 100 mm	Ø 09, 10, 11, 12, 13, 14, 15 mm
04.25.03.XX070	Angulate Stem Extension Modular - 70 mm	Ø 09, 10, 11, 12, 13, 14, 15 mm
04.25.03.XX100	Angulate Stem Extension Modular III - 100 mm	Ø 09, 10, 11, 12, 13, 14, 15 mm

List of the Ancillaries

The ancillary implants of the Cemented Femoral Component are:

- Cemented Base Component;
- Tibial Plateau Component;
- Patellar Component;

The Femoral Component is manufactured from Chromium Cobalt Molybdenum (CrCo) F-75 alloy that fulfills the requirements specified by rule ASTM F-75.

The Plateau Component and the Patellar Component are manufactured from UWMH Polyethylene that fulfills the requirements specified in rule NBR ISO 5834-2.

The correct selection of the models and measures of the Cemented Femoral Component, as well as of its ancillaries to be implanted, is surgeons´ responsibility, as well as it is also his responsibility the

technique adopted, moreover he should be familiar with the material, the application method and the surgical procedure to be adopted.

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 implants should be used. The success is also linked to the rigorous fulfillment of the postoperative cares recommended by the doctor.

The ancillary implants listed below are not object of this registration process, and therefore, should be acquired separately but always from the same manufacturer of the implant or from a supplier indicated by the manufacturer of the implant.

Below follows a list with measures of the ancillary implants to the Cemented Femoral Component:

List of Ancillaries – Cemented Base Component

Code	Description	Available Sizes
04.14.01.000XX	Tibial Base Modular II - Primary	54, 59, 64, 69 mm
04.14.02.000XX	Tibial Base Modular II Revision - Revision	54, 59, 64, 69 mm
04.14.03.000XX	Tibial Base Modular III - Primary	Small, Medium, Large & E. large
04.14.04.000XX	Tibial Base Modular III - Primary	Small, Medium, Large & E. large
04.14.05.000XX	Tibial Base Modular III - Revision	Small, Medium, Large & E. large
04.14.06.000XX	Tibial Base Modular III - Primary - CrCo	Small, Medium, Large & E. large
04.14.07.000XX	Tibial Base Modular III - Revision - CrCo	Small, Medium, Large & E. large

List of Ancillaries – Tibial Plateau Component

Code	Description	Available Sizes
04.17.01.540XX	Tibial Plateau Modular II 54	08, 10, 12, 15, 18, 21, 25 mm
04.17.01.590XX	Tibial Plateau Modular II 59	08, 10, 12, 15, 18, 21, 25 mm
04.17.01.640XX	Tibial Plateau Modular II 64	08, 10, 12, 15, 18, 21, 25 mm
04.17.01.690XX	Tibial Plateau Modular II 69	08, 10, 12, 15, 18, 21, 25 mm
04.17.03.541XX	Tibial Plateau Combined II/III 54	08, 10, 12, 14, 15, 18 mm
04.17.03.591XX	Tibial Plateau Combined II/III 59	08, 10, 12, 14, 15, 18 mm
04.17.03.592XX	Tibial Plateau Combined II/III 59 F	08, 10, 12, 14, 15, 18 mm
04.17.03.641XX	Tibial Plateau Combined II/III 64	08, 10, 12, 14, 15, 18 mm
04.17.03.642XX	Tibial Plateau Combined II/III 64 F	08, 10, 12, 14, 15, 18 mm
04.17.03.643XX	Tibial Plateau Combined II/III 64 F	08, 10, 12, 14, 15, 18 mm
04.17.03.691XX	Tibial Plateau Combined II/III 69	08, 10, 12, 14, 15, 18 mm
04.17.03.693XX	Tibial Plateau Combined II/III 69 F	08, 10, 12, 14, 15, 18 mm
04.17.03.694XX	Tibial Plateau Combined II/III 69 F	08, 10, 12, 14, 15, 18 mm
04.17.02.010XX	Tibial Plateau Modular III Small - Primary	08, 10, 12, 15, 18, 21, 25 mm
04.17.02.020XX	Tibial Plateau Modular III Medium - Primary	08, 10, 12, 15, 18, 21, 25 mm
04.17.02.030XX	Tibial Plateau Modular III Large - Primary	08, 10, 12, 15, 18, 21, 25 mm
04.17.02.040XX	Tibial Plateau Modular III Extra Large - Primary	08, 10, 12, 15, 18, 21, 25 mm
04.17.06.010XX	Tibial Plateau Modular III of Revision Small	10, 12, 15, 18, 21, 25 mm
04.17.06.020XX	Tibial Plateau Modular III of Revision Medium	10, 12, 15, 18, 21, 25 mm
04.17.06.030XX	Tibial Plateau Modular III of Revision Large	10, 12, 15, 18, 21, 25 mm
04.17.06.040XX	Tibial Plateau Modular III of Revision Extra-Large	10, 12, 15, 18, 21, 25 mm
04.17.04.010XX	Tibial Plateau Modular III - P/L Small - Primary	08, 10, 12, 15 mm
04.17.04.020XX	Tibial Plateau Modular III - P/L Medium - Primary	08, 10, 12, 15 mm

04.17.04.030XX	Tibial Plateau Modular III - P/L Large - Primary	08, 10, 12, 15 mm
04.17.04.040XX	Tibial Plateau Modular III - P/L Extra Large - Primary	08, 10, 12, 15 mm

List of the Ancillaries – Patellar Component

Code	Description	Available Sizes
04.16.01.000XX	Biconvex Patellar Component Modular III	26, 28, 30, 32, 34, 36, 38 mm
04.16.02.000XX	Standard Patellar Component	26, 28, 30, 32, 34, 36, 38 mm
04.16.02.000XX	Triple Fixation Patella – Ø 26 mm	26, 28, 30, 32, 34, 36, 38 mm

List of support material

The support materials are instruments destined uniquely for implantation of total prosthesis Modular III and Modular III PL systems, of which the Cemented Femoral Component is part.

These instrumentals are manufactured in stainless steel in accordance with the requirements specified by rule ASTM F899-02 – Standard Specification for Stainless Steel for Surgical Instruments (Standard Specification for Stainless Steel for Surgical Instruments), that supply them high resistance and durability.

The instrumentals below are not object of this registration process, and should, therefore, be acquired separately but always from the manufacturer of the implant or from a supplier indicated by the manufacturer of the implant.

The instrumentals traded by MDT or by a manufacturer indicated by same to perform the implantation surgeries of the Cemented Femoral Component and its accessories are:

- Instrumental Modular II;
- Instrumental Modular III – Primary;
- Instrumental Modular III – Revision;
- Instrumental Modular III/PL

The surgical instrumentals are supplied uncontaminated, but not sterilized. The surgical instruments are subject to wear with normal usage, and consequently, may break.

The instrumentals are only to be used for their intended purposes, and should be regularly inspected for possible wear and damage.

To obtain more information in regards to the instrumental, contact a MDT representative.

Adverse Effects

In addition to the fact that obvious risks can happen in the presence of orthopedic implants, like failure, loosening and fractures, any risks and uncertainties referring to long term effects can be susceptible to occurrence of tissular chronic injury.

Although there is not a connection scientifically proved reference the use of orthopedic implants with the characteristics of the materials used in the manufacturing of the Cemented Femoral Component and the occurrence of cancer, any risks and uncertainties reference long terms effects of articular substitutions, 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 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 tissues can result in inflammatory reactions, which can happen, for example, in the presence of debris arose from implant (like metallic or polyethylene debris), which can cause histiocytic answer, granuloma type of strange body, which can cause bony destruction, associated or not to the loosening of the implant.

Precautions and Warnings

- The Cemented Femoral Component is only to be used together with acrylic bony cement; otherwise there can be failure of the device and progressive loss of bony reserve;

- The use together with devices of other manufacturers can result in incongruence between the components;
- It is advisable to use preventive antibiotic therapy in patients carriers of articular substitutions which are submitted to proceedings that can cause transitory bacteremia (odontological procedures, vesical probing, endoscopy, groin vessels catheterism of inferior members and other minor surgical proceedings);
- The Cemented Femoral Component was conceived to be implanted through the use of instrumental specifically developed for that purpose, and, therefore necessary for insertion and adequate positioning of the implant. Any improvisation with different instrumental or imprecise surgical technique can jeopardize the fixation quality and/or the implant positioning;
- Previously to insertion of the bony cement and of the component, it is advisable to obtain a 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 good stability of the implant;
- Implantation on an inadequate bony bed can cause premature loosening and progressive loss of the bony reserve;
- Patients submitted to knee prosthetic articular reconstruction should be submitted to periodic medical evaluation, so that possible alterations to the implant and to the adjacent bone can be observed;
- Discard and do not use open or damaged devices. Use only devices properly packed in shut and non damaged packages;
- Inadequate sterilization of the surgical instrumental may cause prosthetic infection;
- Do not use the product if its term is due or its package violated;
- The package opening for surgical use should be made by the nursing personnel, who are qualified for that procedure;
- Never reuse an implant. Even though it may not present any external damage, previous efforts can reduce its durability;
- The clinical results and the durability of the implant of femur total arthroplasty are extremely dependent of the tridimensional alignment of the components, being, therefore, essential to apply a precise surgical technique;
- The Cemented Femoral Component is supplied sterile, therefore, should be used immediately after opening the sterilization stamp and should not be used in case there is loss of sterility of the device;
- Do not re-sterilize;
- Date of manufacturing, due date and batch number: see the label.

The patient should be informed of:

All restrictions after surgery, mainly the ones related to sports and occupational activities.

The fact that complications or failures arisen from knee total arthroplasty are much common to occur in:

- Patients with functional expectations beyond the ones offered by the articular substitution;
- Patients with high corporal weight;
- young and/or dynamic patients;
- Patients with small ossature.

The complications in regards to knee arthroplasty procedures, as well as the information listed in the topics: Indications, Contraindications, Adverse Effects, Precautions and Warnings.

The necessity of periodic medical evaluation so that possible alterations in the implant and in the adjacent bone will be observed. Without such evaluation it will not be possible to detect loosening of the components or 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.

It is necessary to inform the fact of being prosthesis carrier, when being submitted to Magnetic Resonance 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.

Children, old aged people, patient with mental problems, and chemical addicts may represent a bigger risk to failure of the device, once these patients tend to ignore instructions and restrictions.

The patient should be instructed, subject to doctor's discretion, to use external supports, aid to wander and orthopedic devices, projected to immobilize the area of the fracture and to limit the weight.

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. To use the product, the following instructions should be followed:

- Sterilize the instrumentals according to the recommended instructions to follow;
- Manipulate the Cemented Femoral Component implants exclusively in proper environment (ambulatory or surgical room), taking adequate manipulation care (manipulate only with sterilized gloves). Only qualified professionals should manipulate and implant the components;
- The Cemented Femoral Component should be applied taking into consideration the exigencies and proper surgical techniques;
- The Cemented Femoral Component should only be used with its respective surgical instrumentals. Any improvisation with different instrumentals or inaccurate surgical technique can jeopardize the fixation quality and/or the implant positioning.
- For application it is essential to use the other corresponding components of the system of knee total prosthesis manufactured by MDT and/or by a manufacturer indicated by same.

Sterilization

The Cemented Femoral Component and its accessories (essential parts) are supplied in the condition of sterile product. The sterilization method adopted is the one by Gamma Radiation.

The production of the Cemented Femoral Component is performed with great care to assure to the surgeon safety and quality of the operative results. The medical personnel should also contribute to obtain the expected surgical result, giving due attention to the handling and use of the devices, mainly with respect to sterilization, so that prosthetic risks are minimized to the maximum.

In regards to the surgical instrumentals used to implant the Cemented Femoral Component, the recommended sterilization method is the one by autoclave, under vacuum, according to the parameters specified by rule NBR 14332:1999 (Surgical and odontological instruments – Orientation on handling, cleaning and sterilizing).

During cleaning and sterilization procedures, the instruments should be carefully inspected before their use; impact instruments with visible signs of usage and wear, as well as blunt cut instruments should not be used.

Cleaning, sterilization and conservation of the instrumentals

When the instruments are to be used for the first time, they should be removed from their packages and cleaned with 70% medicinal alcohol and 30% distilled water.

After cleaning, the products should be rinsed with sterile distilled water and dried with a cleaning cloth that does not release fibers. Detergents with free chlorine or sodium hydroxide **should not** be used.

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

Sterilization by autoclave is a safe sterilization 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]).

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

The recommended sterilization cycle is:

Method	Cycle	Temperature	Time of exposition
Steam	Pre-vacuum	132º - 135º C [270º - 275º F]	Minimum 10 minutes

For conservation of the instrumentals, the following cares should be taken:

- Check if the instruments present signs of wear and damages in all handling stages;
- If any damage is detected, a representative of MDT Indústria e Comércio de Implantes Ortopédicos Ltda should be contacted for technical assistance.

Risk of Contamination

Considering that the Cemented Femoral Component, due to the fact of being an implantable material, 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 bases 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.

After being removed the bases should be discarded and should not be reused under any circumstance.

The implants removed or considered inadequate for use should be destroyed before being discarded. We recommend that the pieces are cut, bent of filed.

To discard the removed bases, it is recommended to follow the local legal procedures for products potentially contaminants in force in the country.

Tracking

To assure tracking of the implanted product and fulfill the Sanitary Authority requirements, we recommend that the surgeon responsible or his team, report to the implant distributor the following information reference the implanted product, patient and the surgery made:

- Name of the surgeon;
- Date of the surgery;
- Name of the patient that received the implant;
- Product Code;
- Batch Number;

The pieces bring the following engraved information:

- Logotype of the Company;
- Manufacturing Batch;
- Piece Code.

It is recommended that the surgeon or his team make use of the labels supplied in 5 copies, available inside the package of the product, gluing them on the patient's promptuary to maintain tracking of the material; besides, it is also recommended that one of those labels is supplied to the patient, so that he has information regarding the implanted material.

The labels contain data of the product like: code, description and batch, among other information.

Storage

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

Do not store the implants directly on the ground (minimum height = 20cm); they 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 the implants in areas where contaminating substances are used, like insecticides, pesticides or cleaning material.

Transportation

Transport the implants with care, avoiding fall and friction, so that no damage is made to the surface of the piece.

Maintain the implants always in their original packages up to the moment of their use, under the responsibility of the doctor/hospital team nominated for that purpose, having in mind that the package integrity has to be always observed.

Date of manufacturing, due date and batch number: see the label. Do not use the product if its date is due.

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: 10417940046
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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