Instructions Use

Patellar Component

Symbols used in packaging

REF		Product Code		Avoid direct exposition at sunlight
LOT		Lot Code		Keep protected of humidity
		Consult instructions for use		Take care - Fragile
Raw Material UHMWPE		Ultra-High-Molecular-Weight Polyethylene (NBR 5834-2)		Do not use if the package is damaged
		Manufacturing date		Validity Date
Sterile	**R**	Sterilized by Gamma Radiation		Single use product

Description:

The Patellar Component has format of spherical cap and substitute partially the patella in the contact region with the knee femoral component.

The raw material used for manufacturing of Patellar Component is the Ultra-High-Molecular-Weight (UHMWPE) Polyethylene.

(As NBR ISO 5834-2 specification).

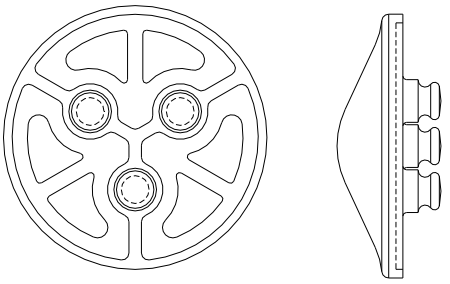
Composition:

The Patellar Component is manufactured in Polyethylene Ultra-High-Molecular-Weight (UHMWPE) Polyethylene, as specification NBR ISO 5834-2.

The Patellar Components are presented in the following models:

	Standard – Modular II

	Biconvex – Modular III

	Triple Fixation

Purpose

The Patellar Component is indicated for use together with knee components others.

It is cemented in the internal part of patella, avoiding the pain that there is due to the contact between bone and the metallic femoral implant.

The Patellar Components are available in the following dimensions:

Table – Patellar Components Description

CODE	DESCRIPTION
04.16.01.00026	Modular III Biconvex Patellar Component Ø 26 mm
04.16.01.00028	Modular III Biconvex Patellar Component Ø 28 mm
04.16.01.00030	Modular III Biconvex Patellar Component Ø 30 mm
04.16.01.00032	Modular III Biconvex Patellar Component Ø 32 mm
04.16.01.00034	Modular III Biconvex Patellar Component Ø 34 mm
04.16.01.00036	Modular III Biconvex Patellar Component Ø 36 mm
04.16.01.00038	Modular III Biconvex Patellar Component Ø 38 mm
04.16.02.00026	Modular II Biconvex Patellar Component Ø 26 mm
04.16.02.00028	Modular II Standard Patellar Component Ø 28 mm
04.16.02.00030	Modular II Standard Patellar Component Ø 30 mm
04.16.02.00032	Modular II Standard Patellar Component Ø 32 mm
04.16.02.00034	Modular II Standard Patellar Component Ø 34 mm
04.16.02.00036	Modular II Standard Patellar Component Ø 36 mm
04.16.02.00038	Modular II Standard Patellar Component Ø 38 mm
04.16.03.00028	Triple Fixation Patellar Ø 28 mm
04.16.03.00030	Triple Fixation Patellar Ø 30 mm
04.16.03.00032	Triple Fixation Patellar Ø 32 mm
04.16.03.00034	Triple Fixation Patellar Ø 34 mm
04.16.03.00036	Triple Fixation Patellar Ø 36 mm
04.16.03.00038	Triple Fixation Patellar Ø 38 mm

IMPORTANT:

For the Patellar Component implantation needs the use of specific instrumental that can be acquired separately of Patellar Component:

The Instrumental Kit for Knee Application is registered by Anvisa under nº 10417940031.

Consult its representative MDT for more information about the instrumental.

The Instrumental Kit for Knee Application is consists of the following items:

Table - Modular II

CODE	DESCRIPTION
02.02.39.00000	Drill Guide for Patella Standard
02.10.03.00002	Drill with Stop Ø 10,0 mm for Standard Patella
02.73.01.00001	Clamp Large for Patella
02.02.11.00059	Cut Guide Femoral Anterior/Posterior 59 mm
02.02.11.00064	Cut Guide Femoral Anterior/Posterior 64 mm
02.02.11.00069	Cut Guide Femoral Anterior/Posterior 69 mm
02.02.16.00059	Cut Guide Intercondylar 59 mm
02.02.16.00064	Cut Guide Intercondylar 64 mm
02.02.16.00069	Cut Guide Intercondylar 69 mm
02.02.14.00005	Femoral Alignment Guide JM-2
02.02.11.00007	Cut Guide Femoral Initial JM-2
02.44.01.00001	Femoral Sizer JM-2
02.02.11.00008	Cut Guide Femoral Forward JM-2
02.10.10.80230	Drill with Straight Cut Ø8,0 X 230 mm
02.38.00.00014	Ostheotome 14 mm
02.38.00.00019	Ostheotome 19 mm
02.13.01.00001	Pin for Simple Fixation
02.13.05.00001	Pin for Guide of Femoral Cut
02.14.07.00000	Femoral Impactor
02.14.06.00000	Tibial Impactor
02.18.15.00059	Femoral Tester 59 mm
02.18.15.00064	Femoral Tester 64 mm
02.18.15.00069	Femoral Tester 69 mm
02.18.17.59008	Tibial Plateau Tester 59 X 8 mm
02.18.17.59010	Tibial Plateau Tester 59 X 10 mm
02.18.17.59012	Tibial Plateau Tester 59 X 12 mm
02.18.17.59015	Tibial Plateau Tester 59 X 15 mm
02.18.17.64008	Tibial Plateau Tester 64 X 8 mm
02.18.17.64010	Tibial Plateau Tester 64 X 10 mm
02.18.17.64012	Tibial Plateau Tester 64 X 12 mm
02.18.17.64015	Tibial Plateau Tester 64 X 15 mm
02.18.17.69008	Tibial Plateau Tester 69 X 8 mm
02.18.17.69010	Tibial Plateau Tester 69 X 10 mm
02.18.17.69012	Tibial Plateau Tester 69 X 12 mm
02.18.17.69015	Tibial Plateau Tester 69 X 15 mm
02.18.18.00030	Patellar Tester Standard 30 mm
02.18.18.00032	Patellar Tester Standard 32 mm

02.18.18.00034	Patellar Tester Standard 34 mm
02.40.00.17500	Spacer 17,5 mm
02.40.00.19000	Spacer 19 mm
02.40.00.21000	Spacer 21 mm
02.40.00.24000	Spacer 24 mm
02.18.19.00059	Tibial Base Tester 59 mm
02.18.19.00064	Tibial Base Tester 64 mm
02.18.19.00069	Tibial Base Tester 69 mm
02.02.40.00059	Guide of Modeler of Tibial Channel 59 mm
02.02.40.00064	Guide of Modeler of Tibial Channel 64 mm
02.02.40.00069	Guide of Modeler of Tibial Channel 69 mm
02.02.36.00059	Cut Guide Chamfered 59 mm
02.02.36.00064	Cut Guide Chamfered 64 mm
02.02.36.00069	Cut Guide Chamfered 69 mm
02.39.01.00001	Support to Initial Cut Guide of Tibia
02.02.12.00003	Initial Cut Guide of Right Tibia
02.02.12.00002	Initial Cut Guide of Left Tibia
02.16.02.00000	Pins Extractor
02.14.15.00001	Impactor for Alignment Guide
02.45.00.20270	File
02.36.01.16155	Small Helicoidally Spring for Traction
02.36.01.16200	Large Helicoidally for Traction
02.35.01.60001	Alignment Bar Ø 6.0 X 472 mm
02.35.01.60002	Alignment Bar with Coupler Ø 6.0 X 472 mm
02.65.01.00002	Distal Femoral Alignment Guide JM-2
02.07.07.00000	Tibial Channel Modeler

Table - Modular III

CODE	DESCRIPTION
02.06.06.35227	Tibial Retractor
02.06.01.24252	Hohmann Retractor 24,5 x 252 mm
02.06.05.48223	Retractor to Tendon Patellar 4,8 x 223 mm
02.23.01.80123	Punch
02.10.04.80127	Combined Femoral Helicoidally Drill Ø 8,0/12,7 mm x 171 mm
02.02.14.00001	Rotational Femoral Alignment Guide
02.10.01.32150	Ø 3,2 mm Helicoidally Drill - 150mm
02.02.14.00000	JM -3 Guide to Line Femoral
02.11.03.28179	Universal Handle
02.02.11.00001	Guide to Previous Femoral Cut
02.02.11.00002	Distal Femoral Cut Guide
02.02.22.00001	Distal Femoral Cut Guide
02.41.01.00000	External Alignment Arc
02.44.01.00000	Femoral Gauge
02.02.11.00003	Small Multiple Femoral Cut Guide
02.02.11.00004	Medium Multiple Femoral Cut Guide
02.02.11.00005	Large Multiple Femoral Cut Guide
02.02.11.00006	Extra-Large Multiple Femoral Cut Guide
02.13.01.31038	Pin to Short Fixation
02.13.01.31055	Pin to Long Fixation
02.13.01.47062	Pin to Reinforced Fixation
02.43.01.45069	Screw to Fixed Ø 4,5 mm

02.16.06.41327	Universal Extractor
02.02.16.00000	Cut Guide Intercondylar
02.38.00.30175	Ostheotome 22 mm
02.45.00.20270	File
02.18.15.01001	Femoral Tester Small Right
02.18.15.01002	Femoral Tester Small Left
02.18.15.02001	Femoral Tester Medium Right
02.18.15.02002	Femoral Tester Medium Left
02.18.15.03001	Femoral Tester Large Right
02.18.15.03002	Femoral Tester Large Left
02.18.15.04001	Femoral Tester Extra-Large Right
02.18.15.04002	Femoral Tester Extra-Large Left
02.02.15.00000	Previous Femoral Guide to Support
02.39.01.00001	Support to Initial Cut Guide of Tibia
02.02.12.00003	Initial Cut Guide of Tibia Right
02.02.12.00002	Initial Cut Guide of Tibia Left
02.02.12.00001	Initial Cut Guide of Tibia Intramedullary
02.37.01.00000	Extensor for Tibial Cut Guide
02.02.20.00001	Tibial Cut Guide
02.02.20.00002	Angular Tibial Cut Guide
02.40.00.08115	Spacer/Alignment Guide 8 mm
02.40.00.10115	Spacer/Alignment Guide 10 mm
02.40.00.12115	Spacer/Alignment Guide 12 mm
02.40.00.15115	Spacer/Alignment Guide 15 mm
02.42.01.00001	Guide Tray for Small Tibial Reamer
02.42.01.00002	Guide Tray for Medium Tibial Reamer
02.42.01.00003	Guide Tray for Large Tibial Reamer
02.42.01.00004	Guide Tray for Extra-Large Tibial Reamer
02.11.10.00000	Special Handle to Tibial Tray
02.10.02.14146	Tibial Drill Ø 14 mm
02.02.13.00014	Intramedullary Tibial Drill Guide
02.15.07.00001	Small/Medium Tibial Reamer
02.15.07.00002	Large/Extra-Large Tibial Reamer
02.25.03.00000	Tibial Reamer Inserter
02.28.03.00000	Drawer Pins Pliers
02.18.12.00001	Small Tibial Base Tester
02.18.12.00002	Medium Tibial Base Tester
02.18.12.00003	Large Tibial Base Tester
02.18.12.00004	Extra-Large Tibial Base Tester
02.14.08.00001	Impactor for Tibial Base Tester
02.18.10.08001	Tibial Plateau Tester S/M 8 mm
02.18.10.10001	Tibial Plateau Tester S/M 10 mm
02.18.10.12001	Tibial Plateau Tester S/M 12 mm
02.18.10.15001	Tibial Plateau Tester S/M 15 mm
02.18.10.08002	Tibial Plateau Tester L/X-L 8 mm
02.18.10.10002	Tibial Plateau Tester L/X-L 10 mm
02.18.10.12002	Tibial Plateau Tester L/X-L 12 mm
02.18.10.15002	Tibial Plateau Tester L/X-L 15 mm
02.16.05.00001	Extractor for Tester of Tibial Base
02.08.14.00001	Clamp Guide to Biconvex Patella
02.15.06.28100	Patellar Reamer Ø 28 mm

02.15.06.30100	Patellar Reamer Ø 30 mm
02.15.06.32100	Patellar Reamer Ø 32 mm
02.15.06.34100	Patellar Reamer Ø 34 mm
02.15.06.36100	Patellar Reamer Ø 36 mm
02.02.10.28000	Guide for Patellar Reamer Ø 28 mm
02.02.10.30000	Guide for Patellar Reamer Ø 30 mm
02.02.10.32000	Guide for Patellar Reamer Ø 32 mm
02.02.10.34000	Guide for Patellar Reamer Ø 34 mm
02.02.10.36000	Guide for Patellar Reamer Ø 36 mm
02.18.09.00028	Biconvex Patellar Tester Ø 28 mm
02.18.09.00030	Biconvex Patellar Tester Ø 30 mm
02.18.09.00032	Biconvex Patellar Tester Ø 32 mm
02.18.09.00034	Biconvex Patellar Tester Ø 34 mm
02.18.09.00036	Biconvex Patellar Tester Ø 36 mm
02.26.03.00000	Patellar Pressurizer
02.05.03.00001	Depth Gauge to Extramedullary Tibial Cut
02.05.03.00000	Depth Gauge to Intramedullary Tibial Cut
02.14.07.00001	Femoral Impactor
02.14.06.00001	Tibial Impactor
02.08.05.00001	Tweezer to Inside the Tibial Plateau
02.08.06.00001	Tweezer to Removing the Tibial Plateau
02.36.01.16155	Small Spring
02.36.01.16200	Large Spring
02.35.01.63001	Alignment Bar
02.35.01.63002	Alignment Bar with Coupler
02.13.03.80262	Intramedullary Tibial Guide Pin
02.02.09.00000	Tibial Ressection Level Guide
02.16.18.00000	Femur Extractor
02.02.30.00000	Patella Drill Guide 3 Points
02.08.14.00000	Guide Tweezer for Patella
02.18.16.00030	Patellar Tester 3 Points Ø 30 mm
02.18.16.00032	Patellar Tester 3 Points Ø 32 mm
02.18.16.00034	Patellar Tester 3 Points Ø 34 mm
02.18.16.00036	Patellar Tester 3 Points Ø 36 mm
02.73.01.00000	Clamp for Patella

Table - Modular III P/L

CODE	DESCRIPTION
02.18.15.01003	Femoral Tester / Modular III Knee P/L / Small Right
02.18.15.01004	Femoral Tester / Modular III P/L Knee / Small Left
02.18.15.02003	Femoral Tester / Modular III P/L Knee / Medium Right
02.18.15.02004	Femoral Tester / Modular III P/L Knee / Medium Left
02.18.15.03003	Femoral Tester / Modular III P/L Knee / Large Right
02.18.15.03004	Femoral Tester / Modular III P/K Knee / Large Left
02.18.15.04003	Femoral Tester / Modular III P/L Knee / X Large Right
02.18.15.04004	Femoral Tester / Modular III P/L Knee / X Large Left
02.18.10.08003	Tibial Plateau Tester 8 mm
02.18.10.10003	Tibial Plateau Tester 10 mm
02.18.10.12003	Tibial Plateau Tester 12 mm
02.18.10.15003	Tibial Plateau Tester 15 mm
02.18.10.08004	Tibial Plateau Tester 8 mm

02.18.10.10004	Tibial Plateau Tester 10 mm
02.18.10.12004	Tibial Plateau Tester 12 mm
02.18.10.12004	Tibial Plateau Tester 16 mm
02.13.08.80000	Stabilization Pin Ø 8,0 mm
02.01.01.60235	Hexagonal Screwdriver 6,0 mm
02.10.03.00003	Drill with Stop Ø8,0 for Knee P/L

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

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

The instrumentals are provided decontaminated, but not sterilized.

Cleaning and Instrumentals Sterilization

When the instruments are used for the first time, they must be removed of their package and cleaning with alcohol for medical ends at 70% + distilled water 30%.

After the cleaning, the products must be rinse with sterile distillate water and dried with cleaning cloth that does not release fibers.

Important

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

Sterilization

After the surgical use, the instrumentals must be cleaned as above described and sterilized by autoclave. The sterilization does not substitute the cleaning and never will be achieved with dirty material.

Autoclaving is a secure sterilization process, however, if there is no control for the operational parameters, can cause damage at the instrumental:

Humidity + High temperature + Oxygen = Corrosion = Microfissure = Crack = Break

The selected sterilization process must meet, in any case, the standard EN556, which establishes the theoretical probability of presence of microorganism vital to a maximum of 1 $x10^{-6}$ (S.A.L. [Sterility Assurance Level] = 10^{-6}).

For cleaning and sterilization, observe the appropriate procedures. As a suggestion, use the standard ASTM F1744:1996.

The recommended sterilization cycle is:

Method	Cycle	Temperature	Exposition Time
Steam	Pre-Vacuum	132º - 135º C [270º - 275º F]	Minimum 10 minutes

Inspection

1. Inspect if the instrument presents signs of wear and damage in all the handling stages;
2. If any damage is detected, consult the representative of the MDT Indústria Comércio Importação e Exportação de Implantes Ltda., for guidelines.

Necessary is too, the use of following ancillary to the implant Patellar Component, which must be supplied separately.

Table – Femoral Component

CODE	DESCRIPTION
04.15.01.00054	Modular II Femoral Component 54 mm
04.15.01.00059	Modular II Femoral Component 59 mm
04.15.01.00064	Modular II Femoral Component 64 mm
04.15.01.00069	Modular II Femoral Component 69 mm
04.15.02.00054	Component Femoral Modular II Revision Right 54mm
04.15.02.00059	Component Femoral Modular II Revision Right 59mm
04.15.02.00064	Component Femoral Modular II Revision Right 64mm
04.15.02.00069	Component Femoral Modular II Revision Right 69 mm
04.15.03.00054	Modular II Revision Femoral Component - Left 54mm
04.15.03.00059	Modular II Revision Femoral Component - Left 59mm
04.15.03.00064	Modular II Revision Femoral Component - Left 64mm
04.15.03.00069	Modular II Revision Femoral Component - Left 69mm
04.15.04.00001	Small Right Modular III Femoral Component
04.15.04.00002	Medium Right Modular III Femoral Component
04.15.04.00003	Large Right Modular III Femoral Component
04.15.04.00004	Extra-Large Right Modular III Femoral Component
04.15.05.00001	Component Femoral Modular III Left Small
04.15.05.00002	Component Femoral Modular III Left Medium
04.15.05.00003	Component Femoral Modular III Left Large
04.15.05.00004	Component Femoral Modular III Left Extra-Large
04.15.06.00001	Component Femoral Modular III P/L Right Small
04.15.06.00002	Component Femoral Modular III P/L Right Medium
04.15.06.00003	Component Femoral Modular III P/L Right Large
04.15.06.00004	Component Femoral Modular III P/L Right Extra-Large
04.15.07.00001	Component Femoral Modular III P/L Left Small
04.15.07.00002	Component Femoral Modular III P/L Left Medium
04.15.07.00003	Component Femoral Modular III P/L Left Large
04.15.07.00004	Component Femoral Modular III P/L Left Extra-Large

The Femoral Component is registered by Anvisa under nº 10417940046.

Table – Base

CODE	DESCRIPTION
04.14.01.00054	Tibial Base Modular II 54 mm
04.14.01.00059	Tibial Base Modular II 59 mm
04.14.01.00064	Tibial Base Modular II 64 mm
04.14.01.00069	Tibial Base Modular II 69 mm
04.14.02.00054	Tibial Base Modular II Revision 54 mm
04.14.02.00059	Tibial Base Modular II Revision 59 mm
04.14.02.00064	Tibial Base Modular II Revision 64 mm
04.14.02.00069	Tibial Base Modular II Revision 69 mm
04.14.03.00001	Tibial Base Modular III – Small

04.14.03.00002	Tibial Base Modular III – Medium
04.14.03.00003	Tibial Base Modular III – Large
04.14.03.00004	Tibial Base Modular III – Extra-Large
04.14.04.00001	Tibial Base Modular III – Small - Revision
04.14.04.00002	Tibial Base Modular III – Medium – Revision
04.14.04.00003	Tibial Base Modular III – Large – Revision
04.14.04.00004	Tibial Base Modular III – Extra Large – Revision

The Tibial Base Component is registered by Anvisa under nº 10417940047.

Table – Plateau Component

CODE	DESCRIPTION
04.17.01.54008	Modular II Tibial Plateau 54 x 8 mm
04.17.01.54010	Modular II Tibial Plateau 54 x 10 mm
04.17.01.54012	Modular II Tibial Plateau 54 x 12mm
04.17.01.54015	Modular II Tibial Plateau 54 x 15mm
04.17.01.54018	Modular II Tibial Plateau 54 x 18mm
04.17.01.54021	Modular II Tibial Plateau 54 x 21mm
04.17.01.54025	Modular II Tibial Plateau 54 x 25mm
04.17.01.59008	Modular II Tibial Plateau 59 x 8 mm
04.17.01.59010	Modular II Tibial Plateau 59 x 10 mm
04.17.01.59012	Modular II Tibial Plateau 59 x 12 mm
04.17.01.59015	Modular II Tibial Plateau 59 x 15mm
04.17.01.59018	Modular II Tibial Plateau 59 x 18mm
04.17.01.59021	Modular II Tibial Plateau 59 x 21mm
04.17.01.59025	Modular II Tibial Plateau 59 x 25mm
04.17.01.64008	Modular II Tibial Plateau 64 x 8mm
04.17.01.64010	Modular II Tibial Plateau 64 x 10mm
04.17.01.64012	Modular II Tibial Plateau 64 x 12mm
04.17.01.64015	Modular II Tibial Plateau 64 x 15mm
04.17.01.64018	Modular II Tibial Plateau 64 x 18mm
04.17.01.64021	Modular II Tibial Plateau 64 x 21mm
04.17.01.64025	Modular II Tibial Plateau 64 x 25 mm
04.17.01.69008	Modular II Tibial Plateau 69 x 8mm
04.17.01.69010	Modular II Tibial Plateau 69 x 10mm
04.17.01.69012	Modular II Tibial Plateau 69 x 12mm
04.17.01.69015	Modular II Tibial Plateau 69 x 15mm
04.17.01.69018	Modular II Tibial Plateau 69 x 18mm
04.17.01.69021	Modular II Tibial Plateau 69 x 21 mm
04.17.01.69025	Modular II Tibial Plateau 69 x 25 mm
04.17.02.01008	Modular III Tibial Plateau Small 08 mm
04.17.02.01010	Modular III Tibial Plateau Small 10mm
04.17.02.01012	Modular III Tibial Plateau Small 12mm
04.17.02.01015	Modular III Tibial Plateau Small 15mm
04.17.02.01018	Modular III Tibial Plateau Small 18 mm
04.17.02.01021	Modular III Tibial Plateau Small 21 mm
04.17.02.01025	Modular III Tibial Plateau Small 21 mm

04.17.02.02008	Modular III Tibial Plateau Medium 08mm
04.17.02.02010	Modular III Tibial Plateau Medium 10mm
04.17.02.02012	Modular III Tibial Plateau Medium 12mm
04.17.02.02015	Modular III Tibial Plateau Medium 15 mm
04.17.02.02018	Modular III Tibial Plateau Medium 18mm
04.17.02.02021	Modular III Tibial Plateau Medium 21mm
04.17.02.03008	Modular III Tibial Plateau Large 08mm
04.17.02.03010	Modular III Tibial Plateau Large 10mm
04.17.02.03012	Modular III Tibial Plateau Large 12mm
04.17.02.03015	Modular III Tibial Plateau Large 15mm
04.17.02.03018	Modular III Tibial Plateau Large 18mm
04.17.02.03021	Modular III Tibial Plateau Large 21mm
04.17.02.04008	Modular III Tibial Plateau Extra-Large 08
04.17.02.04010	Modular III Tibial Plateau Extra-Large 10
04.17.02.04012	Modular III Tibial Plateau Extra-Large 12
04.17.02.04015	Modular III Tibial Plateau Extra-Large 15
04.17.03.54108	Combined Tibial Plateau II/III 54 x 08mm
04.17.03.54110	Combined Tibial Plateau II/III 54 x 10mm
04.17.03.54112	Combined Tibial Plateau II/III 54 x12mm
04.17.03.54114	Combined Tibial Plateau II/III 54 x 14 mm
04.17.03.54115	Combined Tibial Plateau II/III 54 x15mm
04.17.03.54118	Combined Tibial Plateau II/III 54 x 18mm
04.17.03.59108	Combined Tibial Plateau II/III 59 x 08 mm
04.17.03.59110	Combined Tibial Plateau II/III 59 x 10 mm
04.17.03.59112	Combined Tibial Plateau II/III 59 x 12mm
04.17.03.59114	Combined Tibial Plateau II/III 59 x 14 mm
04.17.03.59115	Combined Tibial Plateau II/III 59 x 15mm
04.17.03.59118	Combined Tibial Plateau II/III 59 x 18mm
04.17.03.59208	Combined Tibial Plateau II/III 59 x 08mm/F.
04.17.03.59210	Combined Tibial Plateau II/III 59 x 10mm/F.
04.17.03.59212	Combined Tibial Plateau II/III 59 x 12mm/F.
04.17.03.59215	Combined Tibial Plateau II/III 59 x 15mm/F.
04.17.03.59218	Combined Tibial Plateau II/III 59 x 18mm/F.
04.17.03.64108	Combined Tibial Plateau II/III 64 x 08 mm
04.17.03.64110	Combined Tibial Plateau II/III 64 x 10mm
04.17.03.64112	Combined Tibial Plateau II/III 64 x 12mm
04.17.03.64114	Combined Tibial Plateau II/III 64 x 14 mm
04.17.03.64115	Combined Tibial Plateau II/III 64 x 15mm
04.17.03.64118	Combined Tibial Plateau II/III 64 x 18mm
04.17.03.64208	Combined Tibial Plateau II/III 64 x 08mm/F.
04.17.03.64210	Combined Tibial Plateau II/III 64 x 10mm/F.
04.17.03.64212	Combined Tibial Plateau II/III 64 x 12mm/F.
04.17.03.64215	Combined Tibial Plateau II/III 64 x 15mm/F.
04.17.03.64218	Combined Tibial Plateau II/III 64 x 18mm/F.
04.17.03.64308	Combined Tibial Plateau II/III 64 x 08mm/F.
04.17.03.64310	Combined Tibial Plateau II/III 64 x 10mm/F.
04.17.03.64312	Combined Tibial Plateau II/III 64 x 12mm/F.

04.17.03.64315	Combined Tibial Plateau II/III 64 x 15mm/F.
04.17.03.64318	Combined Tibial Plateau II/III 64 x 18mm/F.
04.17.03.69108	Combined Tibial Plateau II/III 69 x 08mm -
04.17.03.69110	Combined Tibial Plateau II/III 69 x 10mm -
04.17.03.69112	Combined Tibial Plateau II/III 69 x 12mm -
04.17.03.69115	Combined Tibial Plateau II/III 69x15mm -
04.17.03.69118	Combined Tibial Plateau II/III 69x18mm -
04.17.03.69308	Combined Tibial Plateau II/III 69x08mm/F
04.17.03.69310	Combined Tibial Plateau II/III 69x10mm/F
04.17.03.69312	Combined Tibial Plateau II/III 69x12mm/F
04.17.03.69315	Combined Tibial Plateau II/III 69x15mm/F
04.17.03.69318	Combined Tibial Plateau II/III 69x18mm/F
04.17.03.69408	Combined Tibial Plateau II/III 69x08mm/F
04.17.03.69410	Combined Tibial Plateau II/III 69x10mm/F
04.17.03.69412	Combined Tibial Plateau II/III 69x12mm/F
04.17.03.69415	Combined Tibial Plateau II/III 69x15mm/F
04.17.03.69418	Combined Tibial Plateau II/III 69x18mm/F
04.17.04.01008	Modular III Tibial Plateau - P/L Small 08 mm
04.17.04.01010	Modular III Tibial Plateau - P/L Small 10 mm
04.17.04.01012	Modular III Tibial Plateau - P/L Small 12 mm
04.17.04.01015	Modular III Tibial Plateau - P/L Small 15 mm
04.17.04.02008	Modular III Tibial Plateau - P/L Medium 08m
04.17.04.02010	Modular III Tibial Plateau - P/L Medium 10m
04.17.04.02012	Modular III Tibial Plateau - P/L Medium 12m
04.17.04.02015	Modular III Tibial Plateau - P/L Medium 15m
04.17.04.03008	Modular III Tibial Plateau - P/L Large 08
04.17.04.03010	Modular III Tibial Plateau - P/L Large 10
04.17.04.03012	Modular III Tibial Plateau - P/L Large 12
04.17.04.03015	Modular III Tibial Plateau - P/L Large 15
04.17.04.04008	Modular III Tibial Plateau - P/L Extra-Large
04.17.04.04010	Modular III Tibial Plateau - P/L Extra-Large
04.17.04.04012	Modular III Tibial Plateau - P/L Extra-Large
04.17.04.04015	Modular III Tibial Plateau - P/L Extra-Large

The Plateau Component is registered by Anvisa under nº 10417940041.

Consult your representative MDT for more information about the ancillary and instrumentals of the Patellar Component.

Contra Indications

To what medical treatment of general manner may concern, all surgical technique, even when properly applied can present problems, complications and situations in which the final objective is not totally or partially achieved, and being their contra-indications always dependent upon the assistant-surgeon evaluation of the case and criteria, starting from the anatomy, local biology and systemic, the care of planning and preoperative prepare, the execution and application of perfect technique at intra operative and even the socioeconomic and cultural profile and so that there is respect and the patient cooperation the after surgery recommendations and follow-up. However, there are rules to be followed to avoid problems.

Below, are listed some contra indications although concerning (medical criteria), most often related to the implant:

- Active infections in the operated site or in other regions, neuropathic articulation, absence or paresis of muscles that control the knee, progressive neurological disease, bone disease quickly destructive, or osteonecrosis post-irradiation;
- The Patellar Component should not be used if there is not adequate bone support to guarantee implant stability. In these circumstances, the supplemental method of the bone grafting must be used together with autologous or homologous grafting, or even with the help of mesh and accessories;
- The bone necrosis induced by irradiation in consequence of radiotherapy for cancer treatment is contra indication concerning the knee articular substitution, once that the fault of acetabular bone support can lead to the premature loosening of the implant. In these cases, other techniques and implant systems must be used;
- Local circulatory disease, arterial and venous insufficiencies that predisposing to the appearance of dehiscence and skin necrosis, to the appearance or maintenance of infections, problems and thromboembolic phenomena;
- Systemic diseases, which by diminution of local or general defenses or of circulatory conditions can predispose to complications as dehiscence and infections;
- Neurological disorders, that can bring change in bone strength, or neuro-muscular activity that can overload the implant;
- Bone diseases destructive quickly (for example: Charcot arthroplasty, bone tumors, etc.);
- Osteonecrosis, specially post-irradiation can bring infection troubles and dehiscence;
- The presence of the patient particulars conditions which can bring some bio-incompatibility with the metallic alloy used in the manufacturing implant.

The Patellar Component is contra indicated for patients:

- Young who play sportive activities;
- Patients with overweight, above 102 kilograms;
- Patients with previous or actual infectious pathology;
- Patients with dementia or neurological disorders of lower limbs;
- Particular conditions of the patient: senility, alcoholism and infections. These conditions should be carefully investigated by the surgeon, which should alert the patient about risks from these particularities;

The use in the above cases can cause wear and tear or premature loosening of the Patellar Component, by excess of mechanical stress, infection or prosthetic luxation.

The products described here were developed for use in the above described circumstances; such that any other using are considered contra indicated or without scientific substrate that support its use.

Adverse Effects

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

- Though no scientifically proven association between the use of orthopedic implants with the material features as the ones used in the Patellar Prosthesis MDT, and the occurrence of cancer, any risks and uncertainty about the long term articular substitution effects, should be discussed with the patient prior to the surgery. The patient should also be informed that any circumstances that lead to chronic tissue damage may be oncogene. Cancerous tissues found in the implant vicinity may be related factors not linked directly to the implant such as: metastases from primary lung tumors, breast, digestive system and others, or yet due to the 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 material in organic tissues can elicit inflammatory responses that can occur, for example, at presence of debris from implants (as metallic debris or of polyethylene),

which can cause response histiocytic type strange body granuloma of 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 happen with the nickel, cobalt and chrome that are presents in the steel stainless alloy of orthopedic use. The titanium and its alloys of orthopedic use, are less antigenic accentually and have their use recommended in patients with historic of allergies or sensibility to metal;

Precautions

- This Patellar Component only must be used together with the acrylic bone cement, otherwise there will be mechanical failure of device or loss of bone stock;
- The use together with devices from manufacturer others may result in incongruity between the femoral cavity and the implant cavity;
- It is recommended the use of prophylactic antibioticterapy in patients carriers of articular substitution submitted to procedures which cause temporary bacteremia (dental procedures; endoscopy, catheterization of large vessels in the groin and other smaller surgical procedures);
- The Patellar Component was designed to be implanted through the use of instrumental, specifically developed for this purpose. Any improvisation with different instrumentals or inaccurate surgical technique may compromise the quality of fixation and/or the implant positioning;
- It is recommended previously to insertion of the bone cement and component, the obtaining a hemispherical cavity with viable bone bed. In some occasions, reinforcements in the form of bone grafts or containment devices and support may be indicated to restore bone stock and ensure a good stability of the implant;
- The implantation of component under inadequate bone bed can results in premature loosening and progressive loss of bone stock;
- Patients submitted to prosthetic articular reconstruction of knee should have medical monitoring to check possible changes in the implant and in the adjacent bone;
- **SINGLE USE PRODUCT – DO NOT REUSE;**
- **The Patellar Component is supplied sterile by Gamma Radiation;**
- Use immediately after opening of the sterilization seal;
- Discard and DO NOT USE opened or damaged devices. Use only devices that are packaged in closed packages and undamaged;
- **DO NOT** USE in case of loss device sterilize;
- **DO NOT RESTERILIZE.**

The patient must be informed by:

- All the postoperative restrictions, particularly those related to sportive and occupational activities;
- The capacity and willingness of patient to follow these guidelines are one of the most important aspects in a surgical procedure;
- The fact that complications or failures of knee total arthroplasty are more likely to occur in:
- Patients with functional expectative beyond what can be promoted by the articular substitution;
- Patients with overweight, above 102 kilograms;
- Young patients and/or actives;
- Patients with small skeleton;
- Children, elderly, patients with mental disturbs or chemical dependents, may represent a higher risk to the failure implant, because they can disobey the instructions and restrictions;
- Should instruct the patient, the medical criteria that use external supports, aid to ambulate and orthopedic appliances, designed to immobilize the fracture area and to limit the load;
- Should 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;

- The patient should be oriented to inform that is implant user when submitted to Magnetic Resonance examinations;
- The need for periodic medical monitoring to check the alterations of implant and adjacent bone. Only accompanying can detect possible loosening of component or osteolysis occurrence;
- The information listed in this topic “Indications”, “Contra Indications, “Adverse Effects”, “Precautions and Warnings”.

Warnings

- The opening of the package for surgical use should be performed by nursing team that is qualified for this procedure;
- Inadequate sterilization of the surgical instrumental can cause prosthetic infection;
- Do not use the product if the packaging is breached or with the validity expired. The cares with this material is responsibility of qualified team;
- Single use Hospital Medical Product - Discard after explantation. We recommend that the parts are cut, twist or filing for its destruction, but to dispose of this product, observe the local law;
- Never reuse an implant, because even without external appearance of damage, previous tensions can reduce their lifetime;
- All explanted material, damaged or improper for use, should be send to the manufacturer to be destroyed;
- The clinical results and the durability of the implants in the femur total arthroplasty are extremely dependents on an tridimensional align of the components, therefore being indispensable an accurate surgical technique; Handling with care;
- The patient should have periodic medical monitoring to check the conditions of the implant and adjacent bone;
- Should be respected the limit of implant resistance, which varies by type, at risk of its weakening and possible fracture of the material;
- Do not should be used components of different manufacturer;
- The use of different alloys in metallic joints can cause galvanic corrosion of the implant;
- The use of plastic insert little thick can result in premature wear and polyethylene delamination;
- Manufacturing date, validity term and batch number: see label.

Instructions for Use

The surgical techniques vary according to the surgeon choice, which is responsible by the method, type and dimension of products to be used, as well as, the evaluation criteria of the surgical results.

- Make the sterilization of the instrumentals and Patellar Components according to the instructions recommended below.
- Handle the Patellar Components in exclusively adequate locations (ambulatory or operating rooms) with required care (handling only with sterile gloves). Only qualified professionals must handle and implant the Patellar Component.
- The Patellar Components should be applied according to the requirement and adequate surgical techniques;
- The Patellar Components should be used with the respective instrumentals. Any improvisations with different instrumentals or inaccurate surgical technique may compromise the quality of fixation and/or the implant positioning;
- The torque to be applied during the bone insertion depends on bone characteristics. The surgeon must decide which torque to be applies;
- The inadequate fixation at surgery may increase the risk of loosening and migration of the device or tissue to be sustained by him. For a correct fixation is important to have enough quantity and good bone quality, it is very difficult to get a good fixation in a deteriorated bone. Patients with a poor bone quality, such as an osteoporotic bone, presents a higher risk of loosening or failure;

- It is recommended the use of prophylactic antibioticterapy in patients carriers of articular substitution submitted to procedures which cause transient bacteremia (dental procedures; endoscopy, catheterization of large vessels in the groin and other smaller surgical procedures).

Do not use the Patellar Components together with products from other brands, because of having problems of materials incompatibility.

Risk of Contamination

Considering that the Patellar Component come in contact with tissues and corporals fluids, there is the risk of biological contamination and transmission of viral disease, such as hepatitis and HIV, etc. Therefore, the explanted implants should be treated as contaminants potentially materials.

Product Discard

Fall and crushing on hard surfaces can cause damage to the product. Thus, it is necessary the user performs an inspection of the product integrity, when the packaging is opened, and if any abnormality is observed the product should not be used;

After removal of patient, discard all implants, because **should not be reused**.

The explanted implants that are damaged should be unusable for use before of the discard. It is recommended that the parts be cut, twist or filing for its destruction.

To discard the explanted implants, following the legal local procedures of country, for dispose of contaminants potentially products.

Traceability

To ensure the traceability of the implanted product, and comply with the requirements of the sanitary surveillance, it is recommended that the surgeon responsible by implantation notified the Distributor with the following information regarding to the implanted product, the surgery and the patient:

- Surgeon's name;
- Surgery date;
- Name of patient who received the implant;
- Code of product;
- Number of batch of the product;

The Patellar Component is marked in its body with the following information:

- Company logo;
- Manufacturing batch;

Storage

It is recommended dry and airy place, far away of the sunbeam direct incidence.

The implants cannot be stored directly on the floor (minimum height = 20 cm). They cannot stay in high shelves proximate the lamps (for not dry out or delete the package label), cannot be stored in areas where contaminant substances such as insecticides, pesticides or cleaning materials are used.

Transport

Transport with care, avoiding falls and friction that can damage the surface finish. Always observe the packaging integrity.

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, validity term and batch number: see label.

Do not use the product beyond the validity date.

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

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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.