Instructions for Use

EXACTFLEX Stabilized Knee Arthroplasty System

Keys of symbols used on the packaging

	Reference number (filled with product code)		Lot Code
	Sterile Product - Sterilized by Gamma Radiation		Expiry Date
	Manufacturing Date		Single-Use Product
	See instructions for use		Do not re-sterilize
	Do not use if package is damaged		Fragile, handle with care.
	Keep away from sunlight		Temperature Limit (40°C)
	Keep Dry		

Product features and technical specifications

Technical Name: Femoral-tibial-patellar Multi-compartmental Total Arthroplasty System

Trade Name: EXACTFLEX Stabilized Knee Arthroplasty System

Composed by:

- EXACTFLEX Stabilized Femoral Component;
- EXACTFLEX Stabilized Tibial Plateau;
- EXACTFLEX Tibial Base;
- Triple Fixation Patella;

Raw Material:

Femoral Component Tibial Base	Cobalt Chromium Molybdenum Alloy (Co-28Cr-6Mo) - ASTM F75
Tibial Plateau Triple Fixation Patella	Ultra High Molecular Weight Polyethylene (UHMWPE) - ASTM F648

Sterile Product

Sterilization Method: Gamma Radiation (25 kGy)

Expiry date: 05 years (after sterilization date)

Description

The EXACTFLEX Stabilized Knee Arthroplasty System is a set of surgically invasive implantable devices for long-term use, comprising the following components:

- EXACTFLEX Stabilized Femoral Component
- EXACTFLEX Stabilized Tibial Plateau
- EXACTFLEX Tibial Base
- Triple Fixation Patella

The components of the system, once connected, are intended to replace the natural articulation in total knee arthroplasty procedures in patients that, according to clinical evaluation, have good bone stock and adequate varus/valgus stability and/or when the surgeon needs to sacrifice the posterior cruciate ligament.

The EXACTFLEX Stabilized Knee Arthroplasty System is intended to replace the articular surface of the distal femur, proximal tibia and patellar surface during the surgical procedure for total knee joint replacement in skeletally mature individuals. This procedure is performed in circumstances where this joint is impaired because of pathologies such as non-inflammatory degenerative joint disease (osteoarthrosis), traumatic arthritis, ankylosis of non-infectious origin and knee arthrodesis.

The method of fixation to the intramedullary canal of the femur is through cementing, using polymethylmethacrylate (PMMA) bone cement.

System Components

The EXACTFLEX Stabilized Femoral Component presents a metallic extension that adjusts to the femoral intercondyle and two pins that provide greater rotational stability.

It is available for commercialization in five sizes: Extra-Small, Small, Medium, Large and Extra-Large, for left and right knees.

The EXACTFLEX Stabilized Tibial Plateau is intended to be used as an intermediary component between the Femoral Component and Tibial Base. Fixed to the latter through a connection system with a latch, its function is to provide bedding for the condyles of the Femoral Component, avoiding metal-to-metal friction between Femoral Component and Tibial Base.

Its design has a central post, whose purpose is to limit leg extensor movement.

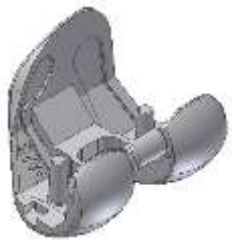
It is available for commercialization in five sizes: Extra-Small, Small, Medium, Large and Extra-large.

The EXACTFLEX Tibial Base presents a bedding plane, where the tibial plateau component fits, and a fixation stem that is cemented into the tibial intramedullary region, providing anterior and posterior rotational stability, besides medial lateral stability.

The component is available for commercialization in five sizes: Extra-Small, Small, Medium, Large and Extra-large.

The Triple Fixation Patella is a spherical cap whose function is to partially replace the patella in the contact region of the femoral component of the knee.

The component is available for commercialization in six different sizes.

			
EXACTFLEX Stabilized Femoral Component	EXACTFLEX Stabilized Tibial Plateau	EXACTFLEX Tibial Base	Triple Fixation Patella

Composition

The materials selected for the manufacturing of the EXACTFLEX Stabilized Knee Arthroplasty System meet the physicochemical and mechanical properties required to achieve the intended performance of the product. The selection considered factors such as the effects of manufacturing, handling, sterilization, storage, and possible reactions of the material with human tissues and body fluids.

The materials for manufacturing are compatible with biological tissues, cells and body tissues with which they come in contact on implantation. This compatibility is proven by clinical history of use in similar applications, available in scientific and clinical literature worldwide. This evidence also applies to possible wear and degradation products of the materials at acceptable levels throughout its use.

Both the material used to manufacture the product and its respective combinations for the articulation and contact surfaces are related in Annexes A, B and C of ABNT NBR ISO 21534 - Implants for non-active surgery - Implants for replacing joints - Specific Requirements. This standard establishes a list of standards for materials considered acceptable for implant manufacturing, based on their proven clinical history of use, reported in scientific and clinical literature.

The EXACTFLEX Stabilized Femoral Component and the EXACTFLEX Tibial Base are manufactured from Co-28Cr-6Mo cobalt chrome molybdenum alloy that complies with the requirements specified by ASTM F-75 - *Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075).*

The components EXACTFLEX Stabilized Tibial Plateau and Triple Fixation Patella are manufactured from Ultra High Molecular Weight Polyethylene (UHMWPE), which meets the requirements specified by ASTM F-648 - *Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants*.

The choice of these materials for the manufacturing of the EXACTFLEX Stabilized Knee Arthroplasty System was based on similarity criteria (results widely described in literature) and on their biocompatibility, physicochemical and mechanical properties proven by these materials specification standards.

Indication and Purpose

The EXACTFLEX Stabilized Knee Arthroplasty System is intended to replace the articular surface of the distal femur, proximal tibia and patellar surface during the surgical procedure for total knee joint replacement in skeletally mature individuals. This procedure is performed in circumstances where this joint is impaired because of pathologies such as non-inflammatory degenerative joint disease (osteoarthrosis), traumatic arthritis, ankyloses of non-infectious origin and knee arthrodesis.

The product is indicated for patients that, according to clinical evaluation, have good bone stock and adequate varus/valgus stability and/or when the surgeon needs to sacrifice the posterior cruciate ligament.

The system was developed for use under the circumstances described above, so that any other uses are considered to be contraindicated or without scientific basis.

Contraindications

The only absolute contraindication for total knee arthroplasty is the presence of localized or systemic active infection. There are other relative contraindications, such as obesity, cognitive disorders, vascular disorders of the lower limbs, paralysis or severe muscle weakness around the joint.

Listed below are the relative contraindications for the use of the device. Only the surgeon in charge can indicate the procedures after a thorough study of the case:

- Patients with general or specific active infections that can lead to complications.
- Patients with general impaired health status and/or immunosuppressed who are unable to undergo a surgical procedure.
- Patients who have sensitivity to foreign bodies. In these specific cases, testing should be performed.
- Patients with osteoporosis and/ or other bone disorders that may compromise the result of the arthroplasty.
- Patients with rapidly destructive bone disease or post irradiation osteonecrosis.
- Patients who suffer from progressive neurological diseases.
- Patients with cardiovascular diseases and local arterial or venous insufficiencies.

- Patients who use narcotic or alcoholic substances or tobacco.
- Patients without adequate bone support to allow for adequate fixation of the implant.
- Patients with absence or paresis of the muscles that control the knee.

The decision to use the product in a particular patient that presents the abovementioned relative contraindications must be the result of a careful individual assessment of the case made by the surgeon, based on his/her experience and judgment.

Form of Presentation

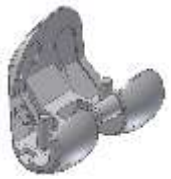
The components that make up the EXACTFLEX Stabilized Knee Arthroplasty System are unitarily packaged in a blister type primary packaging system, sealed with surgical grade paper (Tyvek® type), or in a tubular surgical Tyvek® type package that acts as a sterilization barrier.

The product is available for commercialization in sterile condition and the adopted sterilization method is gamma radiation (25 kGy), a procedure that is performed by a duly qualified third party company.

Once sterilized, the already labeled and primarily packaged components are packed in a cardboard carton (secondary package), which contains five copies of the traceability label and a leaflet with directions on how to obtain the instructions for use for the correct handling of the product.

A label containing information needed for product identification is pasted on the product primary package as well as on its carton.

The EXACTFLEX Stabilized Knee Arthroplasty System is composed by the following components. Each one of these components is available for commercialization in the following dimensions:

Illustrative Image	Code	Description	Sizes	Manufacturing Materials	Qty Packed
	04.15.12.00000	EXACTFLEX Stabilized Right Femoral Component - XS	50 mm x 59 mm	Co-28Cr-6Mo Cobalt Chromium Molybdenum Alloy ASTM F75	01
	04.15.12.01000	EXACTFLEX Stabilized Right Femoral Component - S	54 mm x 64 mm		
	04.15.12.02000	EXACTFLEX Stabilized Right Femoral Component - M	58 mm x 69 mm		
	04.15.12.03000	EXACTFLEX Stabilized Right Femoral Component - L	62 mm x 72 mm		
	04.15.12.04000	EXACTFLEX Stabilized Right Femoral Component - XL	66 mm x 77 mm		
	04.15.13.00000	EXACTFLEX Stabilized Left Femoral Component - XS	50 mm x 59 mm		
	04.15.13.01000	EXACTFLEX Stabilized Left Femoral Component - S	54 mm x 64 mm		
	04.15.13.02000	EXACTFLEX Stabilized Left Femoral Component - M	58 mm x 69 mm		
	04.15.13.03000	EXACTFLEX Stabilized Left Femoral Component - L	62 mm x 72 mm		
	04.15.13.04000	EXACTFLEX Stabilized Left Femoral Component - XL	66 mm x 77 mm		
	04.17.09.00009	EXACTFLEX Stabilized Tibial Plateau 9 mm - XS	62 mm x 42 mm x 9 mm	Ultra-High Molecular Weight Polyethylene (UHMWPE)	01
	04.17.09.00010	EXACTFLEX Stabilized Tibial Plateau 10 mm - XS	62 mm x 42 mm x 10 mm		
	04.17.09.00011	EXACTFLEX Stabilized Tibial Plateau 11 mm - XS	62 mm x 42 mm x 11 mm		
	04.17.09.00012	EXACTFLEX Stabilized Tibial Plateau 12 mm - XS	62 mm x 42 mm x 12 mm		
	04.17.09.00013	EXACTFLEX Stabilized Tibial Plateau 13 mm - XS	62 mm x 42 mm x 13 mm		
	04.17.09.00014	EXACTFLEX Stabilized Tibial Plateau 14 mm - XS	62 mm x 42 mm x 14 mm		
	04.17.09.00015	EXACTFLEX Stabilized Tibial Plateau 15 mm - XS	62 mm x 42 mm x 15 mm		
	04.17.09.00016	EXACTFLEX Stabilized Tibial Plateau 16 mm - XS	62 mm x 42 mm x 16 mm		
	04.17.09.00017	EXACTFLEX Stabilized Tibial Plateau 17 mm - XS	62 mm x 42 mm x 17 mm		
	04.17.09.00018	EXACTFLEX Stabilized Tibial Plateau 18 mm - XS	62 mm x 42 mm x 18 mm		
	04.17.09.00019	EXACTFLEX Stabilized Tibial Plateau 19 mm - XS	62 mm x 42 mm x 19 mm		
	04.17.09.00020	EXACTFLEX Stabilized Tibial Plateau 20 mm - XS	62 mm x 42 mm x 20 mm		
	04.17.09.00021	EXACTFLEX Stabilized Tibial Plateau 21 mm - XS	62 mm x 42 mm x 21 mm		
	04.17.09.00022	EXACTFLEX Stabilized Tibial Plateau 22 mm - XS	62 mm x 42 mm x 22 mm		
	04.17.09.00023	EXACTFLEX Stabilized Tibial Plateau 23 mm - XS	62 mm x 42 mm x 23 mm		
	04.17.09.00024	EXACTFLEX Stabilized Tibial Plateau 24 mm - XS	62 mm x 42 mm x 24 mm		
	04.17.09.00025	EXACTFLEX Stabilized Tibial Plateau 25 mm - XS	62 mm x 42 mm x 25 mm		
	04.17.09.01009	EXACTFLEX Stabilized Tibial Plateau 9 mm - S	67 mm x 42 mm x 9 mm		

	04.17.09.01010	EXACTFLEX Stabilized Tibial Plateau 10 mm - S	67 mm x 42 mm x 10 mm	Ultra-High Molecular Weight Polyethylene (UHMWPE)	01
	04.17.09.01011	EXACTFLEX Stabilized Tibial Plateau 11 mm - S	67 mm x 42 mm x 11 mm		
	04.17.09.01012	EXACTFLEX Stabilized Tibial Plateau 12 mm - S	67 mm x 42 mm x 12 mm		
	04.17.09.01013	EXACTFLEX Stabilized Tibial Plateau 13 mm - S	67 mm x 42 mm x 13 mm		
	04.17.09.01014	EXACTFLEX Stabilized Tibial Plateau 14 mm - S	67 mm x 42 mm x 14 mm		
	04.17.09.01015	EXACTFLEX Stabilized Tibial Plateau 15 mm - S	67 mm x 42 mm x 15 mm		
	04.17.09.01016	EXACTFLEX Stabilized Tibial Plateau 16 mm - S	67 mm x 42 mm x 16 mm		
	04.17.09.01017	EXACTFLEX Stabilized Tibial Plateau 17 mm - S	67 mm x 42 mm x 17 mm		
	04.17.09.01018	EXACTFLEX Stabilized Tibial Plateau 18 mm - S	67 mm x 42 mm x 18 mm		
	04.17.09.01019	EXACTFLEX Stabilized Tibial Plateau 19 mm - S	67 mm x 42 mm x 19 mm		
	04.17.09.01020	EXACTFLEX Stabilized Tibial Plateau 20 mm - S	67 mm x 42 mm x 20 mm		
	04.17.09.01021	EXACTFLEX Stabilized Tibial Plateau 21 mm - S	67 mm x 42 mm x 21 mm		
	04.17.09.01022	EXACTFLEX Stabilized Tibial Plateau 22 mm - S	67 mm x 42 mm x 22 mm		
	04.17.09.01023	EXACTFLEX Stabilized Tibial Plateau 23 mm - S	67 mm x 42 mm x 23 mm		
	04.17.09.01024	EXACTFLEX Stabilized Tibial Plateau 24 mm - S	67 mm x 42 mm x 24 mm		
	04.17.09.01025	EXACTFLEX Stabilized Tibial Plateau 25 mm - S	67 mm x 42 mm x 25 mm		
	04.17.09.02009	EXACTFLEX Stabilized Tibial Plateau 9 mm - M	67 mm x 46 mm x 9 mm		
	04.17.09.02010	EXACTFLEX Stabilized Tibial Plateau 10 mm - M	67 mm x 46 mm x 10 mm		
	04.17.09.02011	EXACTFLEX Stabilized Tibial Plateau 11 mm - M	67 mm x 46 mm x 11 mm		
	04.17.09.02012	EXACTFLEX Stabilized Tibial Plateau 12 mm - M	67 mm x 46 mm x 12 mm		
	04.17.09.02013	EXACTFLEX Stabilized Tibial Plateau 13 mm - M	67 mm x 46 mm x 13 mm		
	04.17.09.02014	EXACTFLEX Stabilized Tibial Plateau 14 mm - M	67 mm x 46 mm x 14 mm		
	04.17.09.02015	EXACTFLEX Stabilized Tibial Plateau 15 mm - M	67 mm x 46 mm x 15 mm		
	04.17.09.02016	EXACTFLEX Stabilized Tibial Plateau 16 mm - M	67 mm x 46 mm x 16 mm		
	04.17.09.02017	EXACTFLEX Stabilized Tibial Plateau 17 mm - M	67 mm x 46 mm x 17 mm		
	04.17.09.02018	EXACTFLEX Stabilized Tibial Plateau 18 mm - M	67 mm x 46 mm x 18 mm		
	04.17.09.02019	EXACTFLEX Stabilized Tibial Plateau 19 mm - M	67 mm x 46 mm x 19 mm		
	04.17.09.02020	EXACTFLEX Stabilized Tibial Plateau 20 mm - M	67 mm x 46 mm x 20 mm		
	04.17.09.02021	EXACTFLEX Stabilized Tibial Plateau 21 mm - M	67 mm x 46 mm x 21 mm		
	04.17.09.02022	EXACTFLEX Stabilized Tibial Plateau 22 mm - M	67 mm x 46 mm x 22 mm		
	04.17.09.02023	EXACTFLEX Stabilized Tibial Plateau 23 mm - M	67 mm x 46 mm x 23 mm		

	04.17.09.02024	EXACTFLEX Stabilized Tibial Plateau 24 mm - M	67 mm x 46 mm x 24 mm	Ultra-High Molecular Weight Polyethylene (UHMWPE)	01
	04.17.09.02025	EXACTFLEX Stabilized Tibial Plateau 25 mm - M	67 mm x 46 mm x 25 mm		
	04.17.09.03009	EXACTFLEX Stabilized Tibial Plateau 9 mm - L	74 mm x 46 mm x 9 mm		
	04.17.09.03010	EXACTFLEX Stabilized Tibial Plateau 10 mm - L	74 mm x 46 mm x 10 mm		
	04.17.09.03011	EXACTFLEX Stabilized Tibial Plateau 11 mm - L	74 mm x 46 mm x 11 mm		
	04.17.09.03012	EXACTFLEX Stabilized Tibial Plateau 12 mm - L	74 mm x 46 mm x 12 mm		
	04.17.09.03013	EXACTFLEX Stabilized Tibial Plateau 13 mm - L	74 mm x 46 mm x 13 mm		
	04.17.09.03014	EXACTFLEX Stabilized Tibial Plateau 14 mm - L	74 mm x 46 mm x 14 mm		
	04.17.09.03015	EXACTFLEX Stabilized Tibial Plateau 15 mm - L	74 mm x 46 mm x 15 mm		
	04.17.09.03016	EXACTFLEX Stabilized Tibial Plateau 16 mm - L	74 mm x 46 mm x 16 mm		
	04.17.09.03017	EXACTFLEX Stabilized Tibial Plateau 17 mm - L	74 mm x 46 mm x 17 mm		
	04.17.09.03018	EXACTFLEX Stabilized Tibial Plateau 18 mm - L	74 mm x 46 mm x 18 mm		
	04.17.09.03019	EXACTFLEX Stabilized Tibial Plateau 19 mm - L	74 mm x 46 mm x 19 mm		
	04.17.09.03020	EXACTFLEX Stabilized Tibial Plateau 20 mm - L	74 mm x 46 mm x 20 mm		
	04.17.09.03021	EXACTFLEX Stabilized Tibial Plateau 21 mm - L	74 mm x 46 mm x 21 mm		
	04.17.09.03022	EXACTFLEX Stabilized Tibial Plateau 22 mm - L	74 mm x 46 mm x 22 mm		
	04.17.09.03023	EXACTFLEX Stabilized Tibial Plateau 23 mm - L	74 mm x 46 mm x 23 mm		
	04.17.09.03024	EXACTFLEX Stabilized Tibial Plateau 24 mm - L	74 mm x 46 mm x 24 mm		
	04.17.09.03025	EXACTFLEX Stabilized Tibial Plateau 25 mm - L	74 mm x 46 mm x 25 mm		
	04.17.09.04009	EXACTFLEX Stabilized Tibial Plateau 9 mm - XL	74 mm x 50 mm x 9 mm		
	04.17.09.04010	EXACTFLEX Stabilized Tibial Plateau 10 mm - XL	74 mm x 50 mm x 10 mm		
	04.17.09.04011	EXACTFLEX Stabilized Tibial Plateau 11 mm - XL	74 mm x 50 mm x 11 mm		
	04.17.09.04012	EXACTFLEX Stabilized Tibial Plateau 12 mm - XL	74 mm x 50 mm x 12 mm		
	04.17.09.04013	EXACTFLEX Stabilized Tibial Plateau 13 mm - XL	74 mm x 50 mm x 13 mm		
	04.17.09.04014	EXACTFLEX Stabilized Tibial Plateau 14 mm - XL	74 mm x 50 mm x 14 mm		
	04.17.09.04015	EXACTFLEX Stabilized Tibial Plateau 15 mm - XL	74 mm x 50 mm x 15 mm		
	04.17.09.04016	EXACTFLEX Stabilized Tibial Plateau 16 mm - XL	74 mm x 50 mm x 16 mm		
	04.17.09.04017	EXACTFLEX Stabilized Tibial Plateau 17 mm - XL	74 mm x 50 mm x 17 mm		
	04.17.09.04018	EXACTFLEX Stabilized Tibial Plateau 18 mm - XL	74 mm x 50 mm x 18 mm		
	04.17.09.04019	EXACTFLEX Stabilized Tibial Plateau 19 mm - XL	74 mm x 50 mm x 19 mm		
	04.17.09.04020	EXACTFLEX Stabilized Tibial Plateau 20 mm - XL	74 mm x 50 mm x 20 mm		

	04.17.09.04021	EXACTFLEX Stabilized Tibial Plateau 21 mm - XL	74 mm x 50 mm x 21 mm	Ultra-High Molecular Weight Polyethylene (UHMWPE)	01
	04.17.09.04022	EXACTFLEX Stabilized Tibial Plateau 22 mm - XL	74 mm x 50 mm x 22 mm		
	04.17.09.04023	EXACTFLEX Stabilized Tibial Plateau 23 mm - XL	74 mm x 50 mm x 23 mm		
	04.17.09.04024	EXACTFLEX Stabilized Tibial Plateau 24 mm - XL	74 mm x 50 mm x 24 mm		
	04.17.09.04025	EXACTFLEX Stabilized Tibial Plateau 25 mm - XL	74 mm x 50 mm x 25 mm		
	04.14.09.00000	EXACTFLEX Tibial Base - XS	42 mm x 62 mm	Co-28Cr-6Mo Cobalt Chromium Molybdenum Alloy ASTM F75	01
	04.14.09.01000	EXACTFLEX Tibial Base - S	42 mm x 67 mm		
	04.14.09.02000	EXACTFLEX Tibial Base - M	46 mm x 67 mm		
	04.14.09.03000	EXACTFLEX Tibial Base - L	46 mm x 74 mm		
	04.14.09.04000	EXACTFLEX Tibial Base - XL	50 mm x 74 mm		
	04.16.03.00026	Triple Fixing Patella Ø 26 mm	Ø 26 mm	Ultra-High Molecular Weight Polyethylene (UHMWPE)	01
	04.16.03.00028	Triple Fixation Patella Ø 28 mm	Ø 28 mm		
	04.16.03.00030	Triple Fixation Patella Ø 30 mm	Ø 30 mm		
	04.16.03.00032	Triple Fixation Patella Ø 32 mm	Ø 32 mm		
	04.16.03.00034	Triple Fixation Patella Ø 34 mm	Ø 34 mm		
	04.16.03.00036	Triple Fixation Patella Ø 36 mm	Ø 36 mm		

The surgeon in charge is responsible for the correct selection of components, dimensions, combinations and the surgical technique for implantation of the system. He/she must be familiar with the material, the application method and the surgical procedure adopted.

The success of the procedure depends on the correct selection, combination, positioning and fixation of the devices, which are responsibilities of the surgeon in charge, who evaluates the patient and decides on the implants to be used. It is also linked to the strict compliance with postoperative care recommended by the surgeon.

Support Material

Support materials are instruments solely designated for implantation of the EXACTFLEX Stabilized Knee Arthroplasty System.

These instruments are manufactured from stainless steel, which meets the requirements specified by ASTM F899 - Standard Specification for Stainless Steel for Surgical Instruments, providing greater strength and durability.

The instruments below are not objects of this registration process and must, therefore, be purchased separately and always from the same manufacturer or from another one, duly appointed by the former.

See listing below for instruments made available by the manufacturer or by another one, duly appointed by the former for implantation of the EXACTFLEX Stabilized Knee Arthroplasty System:

Code	Description
02.02.09.00000	Level Guide of Tibial Ressection
02.02.11.00001	Guide for Anterior Femoral Cut
02.02.11.00002	Guide of Femoral Distal Cut
02.02.11.00003	Guide of Small Multiple Femoral Cut
02.02.11.00004	Guide of Medium Multiple Femoral Cut
02.02.11.00005	Guide of Large Multiple Femoral Cut
02.02.11.00006	Guide of Extra-Large Multiple Femoral Cut
02.02.12.00001	Guide of Initial Intramedullary Cut
02.02.12.00005	Guide of Extramedullary Tibial 7° Cut
02.02.13.00016	Guide of Intramedullary Tibial Ø 16,7mm Drill
02.02.14.00000	Guide of Femoral Alignment JM - 3
02.02.14.00001	Guide of Rotational Femoral Alignment
02.02.15.00000	Guide of Anterior Femoral Support
02.02.16.00001	Guide of Small Intercondyle Cut
02.02.16.00002	Guide of Medium Intercondyle Cut
02.02.16.00003	Guide of Large Intercondyle Cut
02.02.16.00004	Guide of Extra-large Intercondyle Cut
02.02.20.00001	Guide of Tibial Cut out
02.02.20.00002	Guide of Angle Tibial Cut out
02.02.22.00001	Guide of Femoral Distal Cut out
02.02.50.00000	Guide of Femoral Shim Cut / Right Femoral Probe XS
02.02.50.00100	Guide of Femoral Shim Cut / Left Femoral Probe XS
02.05.03.00000	Depth Gauge for Intramedullary Tibial Cut
02.06.01.24252	Hohmann Spacer 24,5 x 252mm
02.06.05.48223	Patellar Tendon Spacer 4,8 x 223 mm
02.06.06.35227	Tibial Spacer
02.08.06.00001	Tibial Plateau Removal Clamp
02.10.01.32150	Smooth Helical Drill Ø 3,5 x 150mm
02.10.01.35001	Smooth Helical Drill Ø 3,5 x 150mm ExactFlex
02.10.02.16146	Helical Drill for Tibial with Quick Coupler Ø16,7 x 146mm
02.10.04.80127	Combined Femoral Helical Drill Ø8,0 / 12,7mm x 171mm
02.10.22.10016	Tibial Drill Ø16mm Exactflex
02.11.03.28179	Universal Handle
02.11.10.00002	Handle for Tibial ExactFlex Tray
02.13.01.31038	Short Fixation Pin
02.13.01.31055	Long Fixation Pin
02.13.01.47062	Reinforced Fixation Pin
02.13.03.80262	Intramedullary Tibial Pin Guide
02.14.06.00001	Tibial Impactor
02.14.06.00003	Tibial Impactor Exactflex
02.14.07.00001	Femoral Impactor
02.14.07.00001	Femoral Impactor ExactFlex
02.14.08.00001	Tibial-Base Probe Impactor
02.14.16.00000	Tibial Plateau Impactor
02.15.07.00005	Small – Medium Primary / Review Tibial Milling Cutter Exactflex
02.15.07.00006	Large – Extra-Large Primary / Review Tibial

Code	Description
02.18.10.18002	Tibial Plateau Probe L/X–L 18mm
02.18.10.21001	Tibial Plateau Probe S/M 21mm
02.18.10.21002	Tibial Plateau Probe L/X–L 21mm
02.18.10.25001	Tibial Plateau Probe S/M 25mm
02.18.10.25002	Tibial Plateau Probe L/X–L 25mm
02.18.12.00000	Extra Small Tibial Base Probe
02.18.12.00001	Small Tibial Base Probe
02.18.12.00002	Medium Tibial Base Probe
02.18.12.00003	Large Tibial Base Probe
02.18.12.00004	Extra-Large Tibial Base Probe
02.18.15.01001	Small Femoral Probe - Right
02.18.15.01002	Small Femoral Probe - Left
02.18.15.02001	Medium Femoral Probe - Right
02.18.15.02002	Medium Femoral Probe - Left
02.18.15.03001	Large Femoral Probe - Right
02.18.15.03002	Large Femoral Probe - Left
02.18.15.04001	Extra-Large Femoral Probe - Right
02.18.15.04002	Extra-Large Femoral Probe - Left
02.23.01.80123	Straight Initial Puncture
02.25.03.00001	Inserter of Tibial Milling Cutter Primary / Review
02.28.03.00000	Pin Extractor Pliers
02.35.01.63001	Alignment bar Ø 6.35 x 406mm
02.35.01.63002	Alignment bar with Coupler
02.36.01.16155	Small Traction Helical Spring
02.36.01.16200	Large Traction Helical Spring
02.37.01.00000	Extensor for Tibial Intramedullary Cut Guide
02.38.00.30175	Osteotome 22mm
02.39.01.00003	Adjustable support for Tibial Extramedullary Cut Guide
02.40.00.09115	Spacer / Alignment Guide 09 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
02.40.00.18115	Spacer / Alignment Guide 18 mm
02.40.00.21115	Spacer / Alignment Guide 21 mm
02.40.00.25115	Spacer / Alignment Guide 25 mm
02.40.00.09000	Spacer / Alignment Guide 09mm Exactflex
02.40.00.10000	Spacer / Alignment Guide 10mm Exactflex
02.40.07.10002	Shim for Spacer / Alignment Guide 02mm Exactflex
02.40.07.10005	Shim for Spacer / Alignment Guide 05mm Exactflex
02.40.07.10008	Shim for Spacer / Alignment Guide 08mm Exactflex
02.40.07.10011	Shim for Spacer / Alignment Guide 11mm Exactflex
02.40.07.10015	Shim for Spacer / Alignment Guide 15mm Exactflex
02.41.01.00000	External Alignment Arc
02.42.01.00017	Guide Tray for Tibial Milling Cutter - XS
02.42.01.00022	Guide Tray for Tibial Small Milling Cutter Primary / Review Exactflex
02.42.01.00023	Guide Tray for Tibial Medium Milling Cutter

	Milling Cutter Exactflex
02.16.05.00001	Tibial Base Probe Extractor
02.16.06.41327	Universal Extractor
02.16.08.00000	Femur Extractor
02.16.10.00010	Femoral Extractor / Impactor Exactflex
02.18.10.09000	Tibial Plateau Probe XS 09mm
02.18.10.09001	Tibial Plateau Probe S/M 09mm
02.18.10.09002	Tibial Plateau Probe L/X–L 09mm
02.18.10.10000	Tibial Plateau Probe XS 10mm
02.18.10.10001	Tibial Plateau Probe S/M 10mm
02.18.10.10002	Tibial Plateau Probe L/X–L 10mm
02.18.10.12000	Tibial Plateau Probe XS 12mm
02.18.10.12001	Tibial Plateau Probe S/M 12mm
02.18.10.12002	Tibial Plateau Probe L/X–L 12mm
02.18.10.15000	Tibial Plateau Probe XS 15mm
02.18.10.15001	Tibial Plateau Probe S/M 15mm
02.18.10.15002	Tibial Plateau Probe L/X–L 15mm
02.18.10.18000	Tibial Plateau Probe XS 18mm
02.18.10.18001	Tibial Plateau Probe S/M 18mm

	Primary / Review Exactflex
02.42.01.00024	Guide Tray for Tibial Small Large Milling Cutter / Review Exactflex
02.42.01.00025	Guide Tray for Tibial Extra-Large Milling Cutter Primary / Review Exactflex
02.43.01.45069	Fixation Screw Ø 4.5mm
02.44.01.00000	Femoral Measurer JM - 3
02.45.00.20270	Rasp
02.75.13.00000	Adapter for Fixation Screw
02.76.04.00000	Femoral Template - XS
02.76.04.00001	Femoral Template - S / M
02.76.04.00002	Femoral Template - L / XL
02.76.04.00000	Femoral Template - XS
02.63.22.03401	Aluminum Case for Modular Knee III 515 x 239 x 95 mm
02.63.22.03402	Aluminum Case for Modular Knee III 515 x 239 x 135 mm
02.63.23.03401	Aluminum Tray 01 for Modular Knee III
02.63.23.03402	Aluminum Tray 02 for Modular Knee III
02.63.23.03403	Aluminum Tray 03 for Modular Knee III
02.63.23.03404	Aluminum Tray 041 for Modular Knee III
02.63.23.03405	Aluminum Tray 05 for Modular Knee III
02.63.23.03406	Aluminum Tray 06 for Modular Knee III

Table 1 - Instruments – EXACTFLEX Stabilized Knee

Code	Description
02.02.30.00000	Drill guide for triple fixation patella
02.08.14.00000	Guide Clamp for patella
02.10.03.00001	Drill with Stop Ø 6,3 mm for triple fixation patella
02.18.16.00028	Triple Fixation Patella Probe Ø 28 mm
02.18.16.00030	Triple Fixation Patella Probe Ø 30 mm
02.18.16.00032	Triple Fixation Patella Probe Ø 32 mm

Code	Description
02.18.16.00034	Triple Fixation Patella Probe Ø 34 mm
02.18.16.00036	Triple Fixation Patella Probe Ø 36 mm
02.18.16.00038	Triple Fixation Patella Probe Ø 38 mm
02.73.01.00000	Patella Clamp
02.63.23.05901	Aluminum Tray for JM3/ JE (Opcional)
02.63.24.00003	Aluminum Case Model 03

Table 2 - Instruments – EXACTFLEX Stabilized Knee (Optional)

The instruments are supplied decontaminated, but not sterilized. Inadequate sterilization of surgical instruments can cause infection.

Surgical instruments are subject to wear during normal use and, therefore, can break. The instruments shall be used only for their intended purposes and shall be inspected regularly to check for possible wear or damage.

For further information about the instruments, consult your representative.

Warnings and Precautions

The team in charge of the procedure must consider the following warnings and precautions to use the product:

- The product shall only be used after a thorough analysis of the surgical procedure to be adopted and a complete reading of the instructions for use;
- The product shall be used only by specialized surgical teams, with specific knowledge and capability about arthroplasty techniques, being the surgeon's responsibility the choice and mastery over the technique to be applied;
- Improper selection and choice of implants to be used, as well as mistakes in indication, handling and application technique can cause excessive tensions and tractions on the implant, possibly leading to failure by fatigue, fracture or implant looseness;
- Clinical results and the durability of the implants are totally dependent on a precise surgical technique;
- The implantation on inappropriate bone bed may cause premature loosening and progressive loss of bone stock;
- The product must be used in conjunction with acrylic bone cement;
- The use in patients with predisposition to disobey medical guidelines and postoperative restrictions, such as children, the elderly, mentally ill and/or chemically addicted people, poses a higher risk of implant failure;
- Risks of implant failure are higher in patients who practice strenuous activities or sports during the postoperative period, contrary to medical restrictions;
- Postoperative complications represent a greater risk when the product is used in patients with functional expectations beyond those that can be delivered by the articular replacement, patients with morbid obesity and patients with small bone structure;

- The product shall not be used if an adequate bone support does not exist to ensure implant stability;
- The patient must submit to periodic medical follow-up to check the conditions of the implant, the bone and adjacent tissues;
- At medical discretion, pre- and perioperative antibiotic prophylaxis, as well as antibiotic therapy, may be adopted in cases of local and / or systemic predisposition or occurrence of infections;
- The implant shall not be used with components from other manufacturers or with different intended purposes. The combination with implants from other manufacturers or with different intended purposes may result in incongruence between components;
- Product identification must be strictly checked and combinations with components from other manufacturers or purposes are not allowed;
- Caring for this material is responsibility of the qualified personnel, which should follow the applicable standards and/or other local regulations;
- Falls or crushing on hard surfaces can cause damage to the product. Therefore, it is necessary that the operator performs an inspection of the product for its integrity when the package is opened, and if any abnormality is observed the product shall not be used;
- The opening of the package for surgical use must be done by nurses qualified for this procedure;
- Do not use the product if it is expired or the packaging is violated;
- Handle with care;
- Single use product – Do not reuse;
- Never reuse an implant. Although they may seem undamaged, previous mechanical stresses applied to them may originate imperfections that would shorten its lifespan in case of re-implantation;
- REPROCESSING PROHIBITED;
- Sterile Product – Do Not Re-Sterilize;
- Manufacturing date, expiry date, and lot number: see label;

Adverse Effects

Every surgical procedure presents risks and the possibility of complications, the infections, bleedings, drug allergic reactions and anesthetic risks being some common ones, among others. The following complications and adverse effects can also be associated with the implantation of the product:

- Loosening, displacement, deformation, implant fracture or osteolysis;
- Postoperative pain, discomfort or abnormal sensations due to the product;
- Reactions to foreign body;
- Inflammatory reactions associated or not to implant loosening and / or displacement;
- Bone necrosis or adjacent soft tissues;
- Breakage of the implant that can make its removal difficult or impractical;

Instructions for Use

For correct use of product, the following instructions must be adopted:

- Caring for this material is responsibility of the qualified personnel, which should follow the applicable standards and/or other local regulations;
- The product shall be handled with due care in appropriate locations (materials central and operating rooms);
- The product shall only be used by specialized surgical teams, with knowledge and specific training on arthroplasty techniques, being the responsibility of the surgeon the choice and mastery over the technique to be applied;
- The established lifespan for the EXACTFLEX Stabilized Knee Arthroplasty System is 10 (ten) years, provided the devices are implanted using a proper surgical technique and taking into account the information on items "Indication and Purpose", "Contraindication", "Warnings and Precautions", and "Instructions for Use";
- For the application of the EXACTFLEX Stabilized Knee Arthroplasty System and its respective ancillaries, it is necessary to use specific instrumentation, as indicated in item "Support

Material", and, because of the possibility of dimensional and / or functional incompatibility, the product shall not be used with instruments other than those indicated by the manufacturer.

- It is necessary to wash and dry the canal in the tibial base component prior to implantation of the other components, to ensure that there is no residual bone or tissue in the joint between the components.
- Before starting the insertion of polymeric components, the surface of the other prosthetic components must be free of debris, such as tissue fragments, bone particles or cement.

Guidance to the Patient and/or Legal Representative

The attending surgical team shall instruct the patient and / or his legal representative on:

- Adequate care and restrictions during the postoperative period. The capacity and willingness of the patient to follow these guidelines are one of the most important aspects in a surgical procedure involving osteosynthesis;
- The fact that risks are greater in patients predisposed to not comply to medical guidelines, care, and postoperative restrictions, such as children, the elderly, subjects with neurological disorders or drug addicts;
- The fact that the product does not substitute and does not have the same performance of normal bone and, therefore, can break, deform or loosen due to excessive physical effort, early load and other situations;
- All postoperative restrictions, especially those related to sports and occupational activities.
- Postoperative complications pose a greater risk to patients with functional expectations beyond what can be promoted by joint replacement, morbidly obese patients, and patients with small bone structure;
- The need to use, exclusively at medical discretion, external support, walking aid, and orthopedic devices designed to limit movements and / or loads;
- The need for periodic medical follow-up, to check the conditions of the implant, bone, and adjacent tissues;
- The fact that not performing revision surgery when components become loose can result in progressive loss of bone stock;
- The fact that implants can interfere with imaging test results. Thus, implant bearers shall report this fact when performing such tests.
- Complications related to knee arthroplasty procedures, as well as the information listed in this item "Guidelines to Patient and / or Legal Representative" and item "Adverse Effects";

Sterilization

The product is supplied in sterile condition. The adopted sterilization method is gamma radiation.

The manufacturing of components is carefully carried out in order to meet the product's intended performance. Thus, the surgical team and others involved shall handle the devices properly so that infection risks are minimized.

Do not use the product if the package is damaged.

Contamination Risk

Since this is an implantable product, when there is need of explantation of components there are also risks of biologic contamination and viral disease transmission.

To minimize these risks, the explanted devices shall be treated as potentially contaminant materials and the applicable standards and/or other local regulations shall be adopted.

Product Disposal

The devices that were explanted or regarded as inappropriate for use must be discarded. It is highly recommended that before discarded, the parts are cut, bent or sanded.

The implants shall be discarded in proper sites, to avoid environmental and other individuals' contamination. The adoption of local regulations for discarding potentially contaminant products is recommended.

Single Use Product – DO NOT REUSE.
REPROCESSING PROHIBITED.

Traceability

To ensure traceability of the implanted product and comply with the health surveillance requirements, the surgeon or his team must register the information about the product in the patient's medical record. Furthermore, such information must be forwarded to the distributor of the product and to the patient, in order to complete the traceability cycle of the implanted product. The necessary information for traceability is relative to the product used, surgery and patient, such as below:

- Name of the patient who received the implant;
- Surgeon's name;
- Hospital's name;
- Manufacturer's name;
- Supplier's name;
- Surgery date;
- Product code;
- Product lot number
- Quantity used;
- Product registration at ANVISA.

The attending surgeon and his team shall make use of the traceability labels provided in the product package, sticking them on the patient's medical record to maintain the traceability of the implanted product. Moreover, one of these labels shall be given to the patient so that he / she has information about the product implanted in the surgical procedure.

The labels bear the product data such as code, description and lot number, among other information.:

- Manufacturer Identification;.
- Component Code;.
- Component Lot Number;
- Component Description (in three languages – Portuguese, English and Spanish);
- Quantity;
- ANVISA registration number;
- Technical name;
- Product commercial name;

Traceability information is necessary for notification by the health service and/or the patients themselves to Sanitary Surveillance Agency - ANVISA and the manufacturer when there is occurrence of serious adverse events, for conducting appropriate investigations.

Storage and Transport

For storage, a dry and airy place is recommended, without light incidence exposure, humidity or contaminating substances.

Since it is a sterile product, temperature and humidity at the storage site shall be monitored and kept below 40 ºC.

The implants cannot be stored directly on the floor. Thus, it is recommended to use shelves with a minimum height of 20 cm.

The product shall be kept in its original packaging until the moment of use and its opening and handling for surgical application shall be carried out by personnel that is trained for this procedure ;

The product shall be properly transported, avoiding falls and friction that may damage the structure and surface of the part.

For information about the date of manufacturing, expiry date, and lot 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: 13.505-600

Phone/Fax: (55-19) 2111-6500

CNPJ: 01.025.974/0001-92

Technician Responsible: Miguel Lopes Monte Júnior – CREA: 0601150192

ANVISA: 10417940118

Review: 00

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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 and COMMERCIAL NAME of the product, informed on its label.

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/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.

MDTImplantes

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