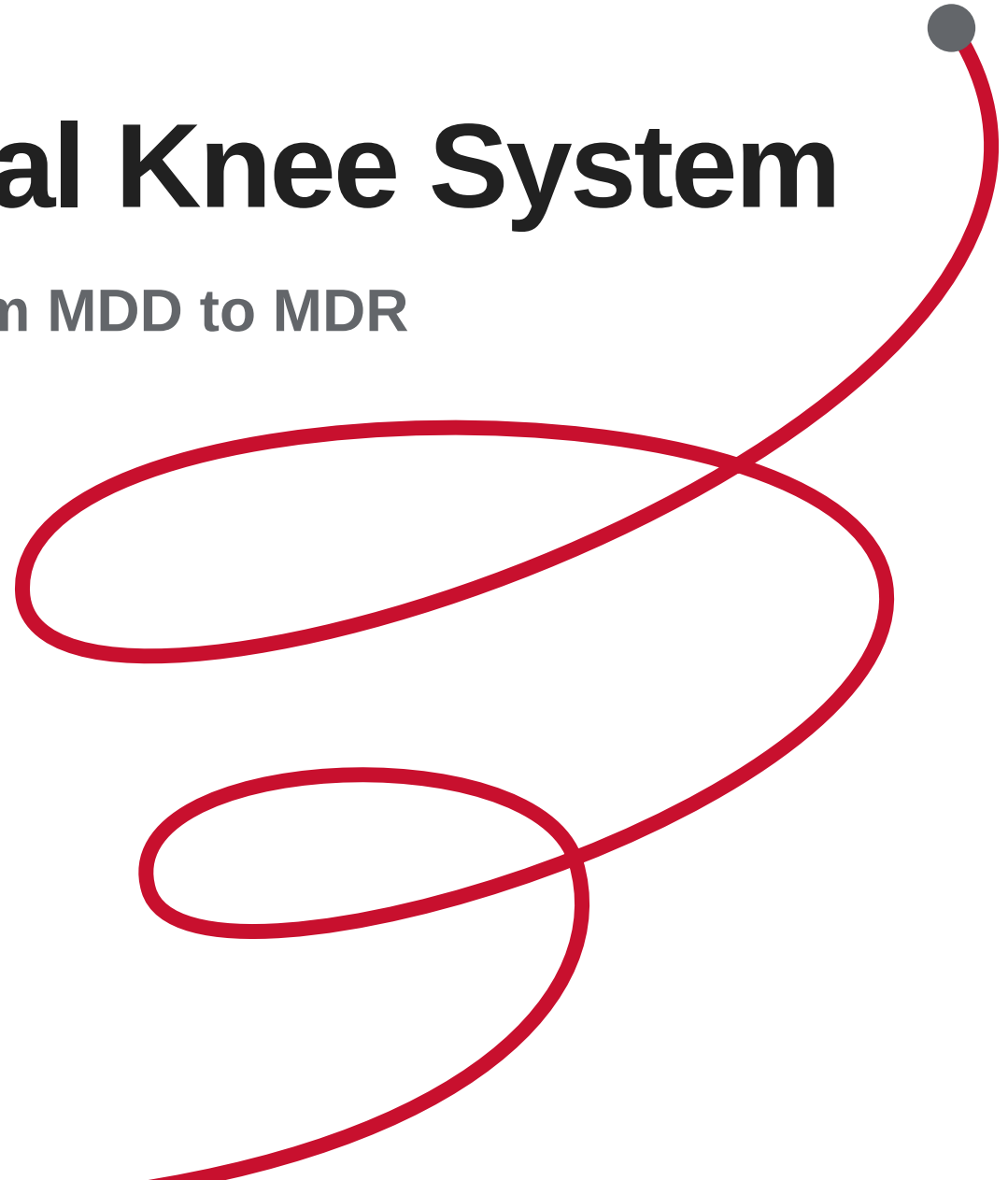
P.F.C.® SIGMA® Total Knee System

Product Information Re Transition from MDD to MDR



DePuy Synthes
THE ORTHOPAEDICS COMPANY OF Johnson&Johnson

Objective | P.F.C.® SIGMA® Total Knee System

Objective

The purpose of this document is to alert you to the EU MDR version of the P.F.C.®™ SIGMA®™ Total Knee System

After reading this document, you will be able to:

- Understand the EU MDR required changes affecting this product
- Find additional product information and reference documents

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Summary of Key Changes| P.F.C.® SIGMA® Total Knee System

Change	Applicable
IFU updated for clinical indication claims or intended use	Yes
IFU updated for clinical contraindication claims	Yes
Additional languages and symbols added to the EU labels	Yes
IFU general updates and rewording	Yes
eIFU Available	Yes
Restricted substances symbols added to Labels and IFU	Yes
Well Established Technology (WET)	No
Patient Implant Card to comply with Article 18	Yes
Patient Target Group	Yes
Warnings/Precautions	Yes
Expected Clinical Benefits	Yes
Adverse Events/Side-Effects	Yes
IFU updates for reprocessing of reusable instruments	No
IFU updates for processing of single-use implants	No

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Details of MDR Changes

MDD vs. MDR - Intended Use

MDD

Total and Unicompartmental Knee Prosthesis

Total or unicompartmental knee arthroplasty is intended to provide increased patient mobility and reduced pain by replacing the damaged knee joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total or unicompartmental knee replacement may be considered for younger patients if, in the opinion of the surgeon, an unequivocal indication for total or unicompartmental knee replacement outweighs the risks associated with the age of the patient, and if limited demands regarding activity and knee joint loading can be assured. This includes severely crippled patients with multiple joint involvement for whom a gain in knee mobility may lead to an expectation of significant improvement in the quality of their lives.

MDR

The P.F.C SIGMA® Knee System is intended to replace articulating elements of a damaged knee joint where there is evidence of sufficient sound bone to seat and support the components.

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MDD vs. MDR – Indications for Use

MDD

Total and Unicompartmental Knee Prosthesis

Candidates for total or unicompartmental knee replacement include patients with

• A severely painful and/or severely disabled joint resulting from osteoarthritis, post-traumatic arthritis, rheumatoid arthritis, or a failed previous implant.

• In candidates for unicompartmental knee arthroplasty, only one side of the joint (the medial or lateral compartment) is affected.

THE SIGMA® C/R POROCOAT® FEMORAL COMPONENTS ARE INTENDED FOR CEMENTED OR CEMENTLESS USE AS THE FEMORAL COMPONENT OF A TOTAL KNEE REPLACEMENT SYSTEM.

IN THE US ALL OTHER POROUS COATED COMPONENTS HAVE BEEN CLEARED FOR CEMENTED USE ONLY.

ANY NON-POROUS COATED COMPONENTS ARE INTENDED FOR CEMENTED USE ONLY.

MDR

1. A severely painful and/or disabled joint (typically due to non inflammatory degenerative joint disease)

2. Failed previous knee surgery.

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MDD vs. MDR – Indications for Use continued

MDD

LCS COMPLETE™ - P.F.C.® SIGMA® RP Mobile Bearing Total Knee System

USE WITH CEMENT:

The LCS COMPLETE™ – P.F.C.® SIGMA® RP Mobile Bearing Total Knee System is indicated for cemented use in cases of osteoarthritis and rheumatoid arthritis. The RPF and RPS inserts and femoral components are indicated where a higher than normal degree of post-operative flexion is required. The rotating platform prosthesis and modular revision components are indicated for revision of failed knee prostheses.

USE WITHOUT CEMENT:

The porous coated Keeled and Non Keeled M.B.T. (Mobile Bearing Tibial) Tray configurations of the LCS Total Knee System are indicated for noncemented use in skeletally mature individuals undergoing primary surgery for reconstructing knees damaged as a result of noninflammatory degenerative joint disease (NIDJD) or either of its composite diagnoses of osteoarthritis and post-traumatic arthritis pathologies. The Rotating Platform device configuration is indicated for use in knees whose anterior and posterior cruciate ligaments are absent or are in such condition as to justify their sacrifice. The P.F.C.® SIGMA® RP Curved bearings when used with the P.F.C.® SIGMA® Cruciate Retaining femoral component can be used in posterior cruciate ligament retaining procedures.

MDR

1. A severely painful and/or disabled joint (typically due to non inflammatory degenerative joint disease)

2. Failed previous knee surgery.

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MDD vs. MDR – Indications for Use continued

MDD

P.F.C.® SIGMA® and P.F.C.® Modular Knee System – Patella

The P.F.C.® SIGMA® and P.F.C.® Modular Knee System—Patella components are indicated for use in knee replacements for patients suffering from severe pain and disability due to permanent structural damage in the knee joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, or pseudogout. This damage may also be the result of trauma or failed prior surgical intervention.

The P.F.C.® SIGMA® and P.F.C.® Modular Knee System—Patella components are indicated for use only with PMMA bone cement.

MDR

1. A severely painful and/or disabled joint (typically due to non inflammatory degenerative joint disease)

2. Failed previous knee surgery.

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MDD vs. MDR - Contraindications

MDD

Total and Unicompartmental Knee Prosthesis

The following conditions are contraindications for total or unicompartmental knee replacement:

1. Active local or systemic infection.

2. Loss of bone or musculature, osteoporosis, neuromuscular compromise or vascular deficiency in the affected limb in sufficient degree to render the procedure unjustifiable (e.g., absence of musculoligamentous supporting structures, joint neuropathy).

3. Severe instability secondary to advanced loss of osteochondral structure or the absence of collateral ligaments.

4. Unicompartmental knee replacement is contraindicated in patients with a severe (over 30°) fixed valgus or varus deformity.

NOTE: Diabetes, at present, has not been established as a contraindication. However, because of the increased risk for complications such as infection, slow wound healing, etc., the physician should carefully consider the advisability of knee replacement in the severely diabetic patient.

MDR

The following conditions are contraindications for total knee replacement:

1. Active local or systemic infection.

2. Loss of bone, musculature or soft tissue conditions or vascular deficiency of the affected limb that would result in inadequate structural or neuromuscular support of the implant system.

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MDD vs. MDR – Contraindications Continued

MDD

LCS COMPLETE™ - P.F.C.® SIGMA® RP Mobile Bearing Total Knee System

FOR USE WITH AND WITHOUT CEMENT:

The use of the LCS COMPLETE – P.F.C.® SIGMA® RP Mobile Bearing Total Knee System is contraindicated in:

• the presence of osteomyelitis, pyrogenic infection or other overt infection of the knee joint. Every effort should be made to rule out the possibility of preoperative sepsis in a patient who has one or more of the following abnormalities:

• fever or local inflammation;

• rapid destruction or bone resorption apparent on x-rays;

elevation of the erythrocyte sedimentation rate or white blood cell count unexplained by other disease or a marked shift in the white blood cell differential count.

• patients with any active infection at sites such as the genitourinary tract, pulmonary system, skin or any other site. Should a patient have any infection prior to implantation, the foci of the infection must be treated prior to, during and after implantation.

• patients with loss of musculature or neuromuscular compromise leading to loss of function in the involved limb or in whom the requirements for its use would affect recommended rehabilitation procedures.

• patients with severe osteoporosis or other metabolic bone diseases of the knee;

• patients with any of the following conditions:

• lesions of the supporting bone structures (e.g. aneurysmal or simple bone cysts, giant cell tumor or any malignant tumor),

• systemic and metabolic disorders leading to progressive deterioration of solid bone support,

• the presence of severe instability secondary to advanced loss of osteochondral structure or the absence of collateral ligaments, fixed deformities greater than 60° of flexion, 45° of genu varus or valgus,

• known drug or alcohol addiction,

• skeletally immature individuals and the presence of allergic reaction to implant metals or polyethylene are also contraindications for the noncemented, porous coated, M.B.T. and LCS COMPLETE – P.F.C.® SIGMA® RP Mobile Bearing device configurations, and for the cemented use of all device configurations of the LCS COMPLETE – P.F.C.® SIGMA® RP Mobile Bearing Total Knee System.

FOR USE WITHOUT CEMENT:

(All Porous Coated Keeled and Non-Keeled M.B.T. Tray Device Configurations Only)

Noncemented use of the Porous Coated Keeled or Non-Keeled M.B.T. Tray device configurations is contraindicated in patients with sufficient loss in quantity or quality of bone stock (as determined on x-ray) such that successful noncemented fixation is unlikely. Additional contraindications may become apparent at the time of surgery.

These include:

• vascular deficiency at the bone site;

• inadequate bone stock to assure both a firm press fit and close apposition of the cut bone surfaces to the prosthesis;

• the inability to make bone cuts so as to assure both correct component position and intimate apposition of bone and prosthetic surfaces;

• inadequate bone quality (e.g. severe osteoporosis) and lack of stability of the implanted components.

In the presence of any of the above conditions, noncemented implantation of the Porous Coated Keeled or Non-Keeled M.B.T. Tray device configurations of the LCS

COMPLETE – P.F.C.® SIGMA® RP Mobile Bearing Total Knee System is contraindicated, and the components should be fixed with cement.

MDR

The following conditions are contraindications for total knee replacement:

1. Active local or systemic infection.

2. Loss of bone, musculature or soft tissue conditions or vascular deficiency of the affected limb that would result in inadequate structural or neuromuscular support of the implant system.

MDD vs. MDR – Contraindications Continued

MDD

P.F.C.® SIGMA® and P.F.C.® Modular Knee System - Patella

Use is contraindicated in cases with active or recent joint sepsis, insufficient bone stock,

skeletal immaturity, inadequate soft tissue coverage or support, Charcot arthropathy,

significant muscular or neuromuscular compromise or psychosocial disorders that would limit rehabilitation.

MDR

The following conditions are contraindications for total knee replacement:

1. Active local or systemic infection.

2. Loss of bone, musculature or soft tissue conditions or vascular deficiency of the affected limb that would result in inadequate structural or neuromuscular support of the implant system.

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MDD vs. MDR – New Sections in IFU

Patient Population

The P.F.C.® SIGMA® Knee System is intended for use is in skeletally mature patients with a severely painful knee and impaired knee function where there is evidence of sufficient sound bone to seat and support the components.

Intended User

These devices are not to be used by unqualified personnel. It is essential that the surgeon and operating room staff are fully conversant with the appropriate surgical technique for the implant and associated instruments.

Expected Clinical Benefits

Total knee arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged knee joint articulation in skeletally mature patients where there is evidence of sufficient sound bone to seat and support the components.

Materials, Summary of Safety and Clinical Performance and Reporting of Serious Incidents

Please see the relevant sections of the new MDR IFU.

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Restricted Substances | P.F.C.® SIGMA® Total Knee System

One or more components of this device contains the following substance(s) defined as CMR 1B in a concentration above 0.1% weight by weight:

Cobalt; CAS No. 7440-48-4; EC No. 231-158-0

Current scientific evidence supports that medical devices manufactured from cobalt alloys or stainless steel alloys containing cobalt **do not** cause an increased risk of cancer or adverse reproductive effects.

For further information on Restricted Substances please refer to the Restricted Substance (RS) Primer & Fact Sheet.

IFU number: IFU-0902-60-064

Article 18 (Implant Card) | P.F.C.® SIGMA® Total Knee System

As this is a non-WET* device, an Implant Card is required to be supplied with the implanted device.

- *WET – well established technology including but not limited to sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors.

IFU number: IFU-0902-60-064

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Product Information

Product Information | Reference Documents

- For the most up to date **Surgical Technique Guides** and **Product Catalogues** linked to these brands, please contact your local Customer Service Team or Johnson & Johnson MedTech Sales Representative.

- Should you have any **medical**, **scientific** or **technical** questions, please submit them to our Medical Affairs team via the **Medical Information Requests (MIR)** portal link:

  Medical Information Request (MIR)

- The **EU MDR Resource Centre** retains other relevant MDR information can be found via the following link:

  EU MDR Resource Centre

- For more information about products and information please refer to the e-IFU page of this document.

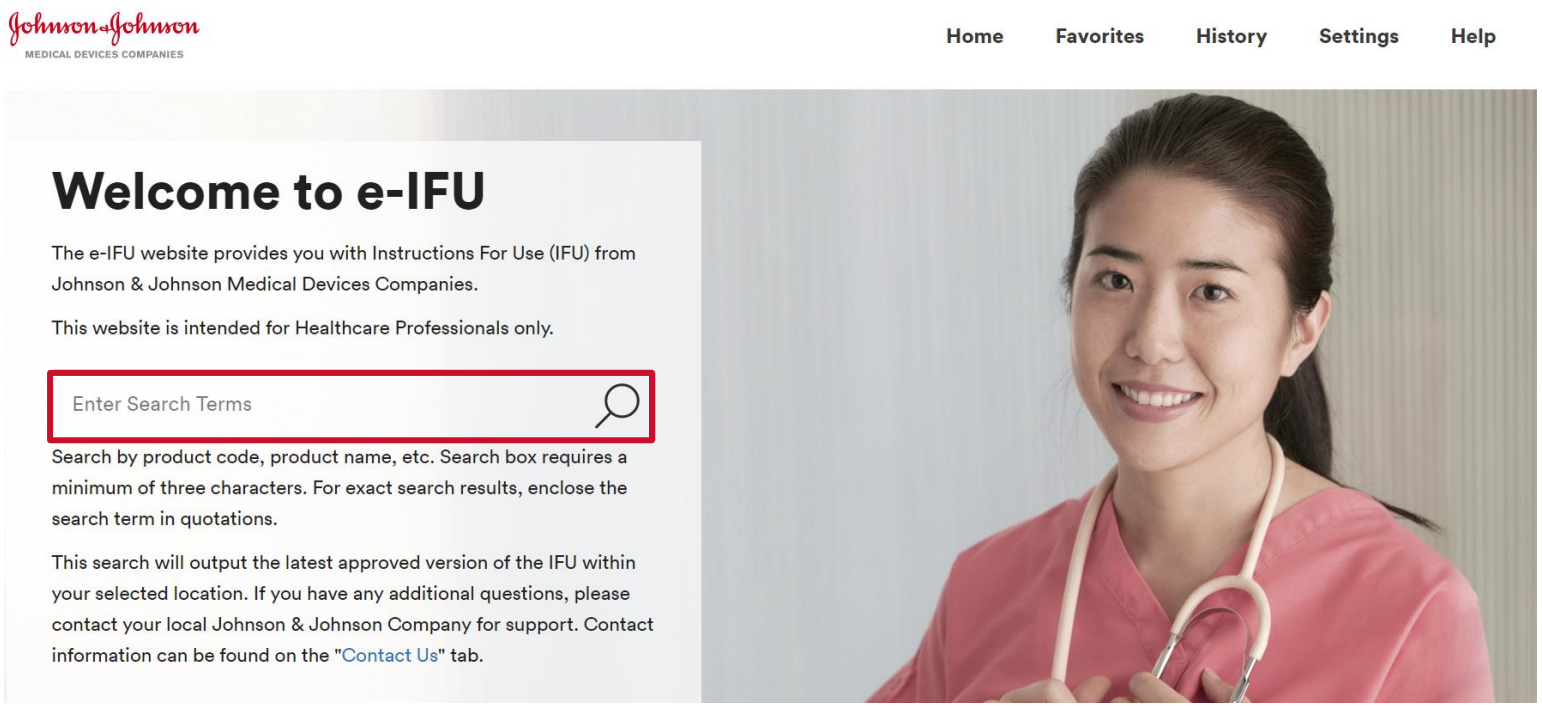
Product Information | Reference Documents (IFU)

Use portal link below, with this information the relevant IFU(s) can be found with the SKU:

MDR: https://www.e-ifu.com/

ePIL (Patient Information Leaflet) on www.ic.jnjmedicaldevices.com

Please refer to the instructions for use for a complete list of indications, contraindications, warnings and precautions.



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Further Information

Restricted Substance (RS) Primer & Fact Sheet

Note:

Presence of Restricted Substance (RS) such as cobalt, Hazardous Substance (HS) symbols have been added to the IFU and labels.

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If you have questions, please contact your local customer service team or Johnson & Johnson MedTech sales representative. Alternatively, if you have any medical, scientific or technical questions please submit these questions to our Medical Affairs team via the Medical Information Requests (MIR) portal: Medical Information Request (MIR).

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