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### **URGENT FIELD SAFETY NOTICE**

Product Name: Medial Rotation Knee™ (MRK™)  
Reference: FSN-21-007  
Action Type: Field Safety Notice on Medical Device – Read updated IFU  
Date: 18 October 2021  
Device Type: Total Knee Replacement

Reason for this Field Safety Notice:

This FSN is to inform you that the indications and contraindications in the current instructions for use for these devices have been updated to reflect the post market surveillance (PMS) data presented at the last product approval which was completed in May 2021.

Root Cause:

The previous indications and contraindications were too general and were not specific to each product family. Whilst they were acceptable when they were originally used, clinical practise has evolved and the PMS data now available can be used to make them more specific and reflective of current clinical practice.

Revised indications for use:

The indication for use of joint replacement prostheses include painful and disabled joint resulting from:

1. osteoarthritis,
2. inflammatory arthritis,
3. post-traumatic arthritis, where one or more compartments are involved.

Patient selection factors which should be considered include:

1. need to obtain pain relief and improve mobility,
2. ability and willingness of the patient to follow instructions,
3. a good nutritional state of the patient, and
4. the patient must have reached full skeletal maturity.

Revised contraindications for use:

Contraindications include:

1. infection,
2. sepsis,
3. osteoporosis,
4. metabolic disorder, or a condition of marked bone loss which could impair bone formation,

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5. vascular insufficiency, muscular atrophy, or neuromuscular disease,
6. uncooperative patient,
7. distant foci of infection (which may cause hematogenous spread to the implant site),
8. incompetent or deficient soft tissue surrounding the joint: your surgeon is best placed to make an assessment of your medical condition for this device.

Additional information:

Additional information is provided in the IFU.

Please read to current instructions for use which can be found at the following:

<https://info.matortho.com/reg/400-477.pdf>

The legal manufacturer for these devices is:

MatOrtho Limited  
19/20 Mole Business Park  
Randalls Road  
Leatherhead  
England  
KT22 7BA  
SRN: GB-MF-000007614

The EU Authorised Representative for these devices is:

MatOrtho Ireland  
The Black Church  
Saint Mary's Place  
Dublin  
Ireland  
D07 P4AX  
SRN: IE-AR-000006856

[AR@matortho.eu](mailto:AR@matortho.eu)

The EU Importer for these devices is:

MatOrtho Europe BV  
Tour & Taxis  
Havenlaan 86C  
Box 204  
1000 Brussels  
Belgium  
SRN: BE-IM-000007870

Dissemination of this FSN:

This FSN has been sent to all current users of the device.

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Please pass this Field Safety Notice to all those who need to be aware of it and, if relevant, pass the FSN on to any another organization where the device may have been transferred

The relevant National Competent Authorities have been advised of the FSN.

All lots of the following devices:

Catalogue Number	Description	GMDN Code	EMDN Code	UDI-DI	Basic-UDI-DI
156-010	Medial Rotation Knee™ Femoral Comp.Pegged Left F0	32831	P0909030101	05055455503373	0505545550000166E
156-011	Medial Rotation Knee™ Femoral Comp.Pegged Left F1	32831	P0909030101	05055455503380	0505545550000166E
156-012	Medial Rotation Knee™ Femoral Comp.Pegged Left F2	32831	P0909030101	05055455503397	0505545550000166E
156-013	Medial Rotation Knee™ Femoral Comp.Pegged Left F3	32831	P0909030101	05055455503403	0505545550000166E
156-014	Medial Rotation Knee™ Femoral Comp.Pegged Left F4	32831	P0909030101	05055455503410	0505545550000166E
156-015	Medial Rotation Knee™ Femoral Comp.Pegged Left F5	32831	P0909030101	05055455503427	0505545550000166E
156-020	Medial Rotation Knee™ Femoral Comp.Pegged Right F0	32831	P0909030101	05055455503434	0505545550000166E
156-021	Medial Rotation Knee™ Femoral Comp.Pegged Right F1	32831	P0909030101	05055455503441	0505545550000166E
156-022	Medial Rotation Knee™ Femoral Comp.Pegged Right F2	32831	P0909030101	05055455503458	0505545550000166E
156-023	Medial Rotation Knee™ Femoral Comp.Pegged Right F3	32831	P0909030101	05055455503465	0505545550000166E
156-024	Medial Rotation Knee™ Femoral Comp.Pegged Right F4	32831	P0909030101	05055455503472	0505545550000166E
156-025	Medial Rotation Knee™ Femoral Comp.Pegged Right F5	32831	P0909030101	05055455503489	0505545550000166E
156-110	Medial Rotation Knee™ Femoral Comp.Stemmed Left F0	32831	P0909030101	05055455503496	0505545550000176G

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Company registered in England: 7323441

Catalogue Number	Description	GMDN Code	EMDN Code	UDI-DI	Basic-UDI-DI
156-111	Medial Rotation Knee™ Femoral Comp.Stemmed Left F1	32831	P0909030101	05055455503502	0505545550000176G
156-112	Medial Rotation Knee™ Femoral Comp.Stemmed Left F2	32831	P0909030101	05055455503519	0505545550000176G
156-113	Medial Rotation Knee™ Femoral Comp.Stemmed Left F3	32831	P0909030101	05055455503526	0505545550000176G
156-114	Medial Rotation Knee™ Femoral Comp.Stemmed Left F4	32831	P0909030101	05055455503533	0505545550000176G
156-115	Medial Rotation Knee™ Femoral Comp.Stemmed Left F5	32831	P0909030101	05055455503540	0505545550000176G
156-120	Medial Rotation Knee™ Femoral Comp.Stemmed Right F0	32831	P0909030101	05055455503557	0505545550000176G
156-121	Medial Rotation Knee™ Femoral Comp.Stemmed Right F1	32831	P0909030101	05055455503564	0505545550000176G
156-122	Medial Rotation Knee™ Femoral Comp.Stemmed Right F2	32831	P0909030101	05055455503571	0505545550000176G
156-123	Medial Rotation Knee™ Femoral Comp.Stemmed Right F3	32831	P0909030101	05055455503588	0505545550000176G
156-124	Medial Rotation Knee™ Femoral Comp.Stemmed Right F4	32831	P0909030101	05055455503595	0505545550000176G
156-125	Medial Rotation Knee™ Femoral Comp.Stemmed Right F5	32831	P0909030101	05055455503601	0505545550000176G
156-351	Medial Rotation Knee™ Tibia Metal Back T1, 50 Stem	32832	P090903020104	05055455503618	0505545550000186J
156-352	Medial Rotation Knee™ Tibia Metal Back T2, 50 Stem	32832	P090903020104	05055455503625	0505545550000186J
156-353	Medial Rotation Knee™ Tibia Metal Back T3, 50 Stem	32832	P090903020104	05055455503632	0505545550000186J

Catalogue Number	Description	GMDN Code	EMDN Code	UDI-DI	Basic-UDI-DI
156-381	Medial Rotation Knee™ Tibia Metal Back T1, 80 Stem	32832	P090903020104	05055455503649	0505545550000186J
156-382	Medial Rotation Knee™ Tibia Metal Back T2, 80 Stem	32832	P090903020104	05055455503656	0505545550000186J
156-383	Medial Rotation Knee™ Tibia Metal Back T3, 80 Stem	32832	P090903020104	05055455503663	0505545550000186J
156-384	Medial Rotation Knee™ Tibia Metal Back T4, 80 Stem	32832	P090903020104	05055455503670	0505545550000186J
156-385	Medial Rotation Knee™ Tibia Metal Back T5, 80 Stem	32832	P090903020104	05055455503687	0505545550000186J
156-511	Medial Rotation Knee™ Left Tibial Insert Size 1, 8mm	46585	P090903020202	05055455503694	05055455500002167
156-512	Medial Rotation Knee™ Left Tibial Insert Size 1, 10.5mm	46585	P090903020202	05055455503700	05055455500002167
156-513	Medial Rotation Knee™ Left Tibial Insert Size 1, 13mm	46585	P090903020202	05055455503717	05055455500002167
156-514	Medial Rotation Knee™ Left Tibial Insert Size 1, 15.5mm	46585	P090903020202	05055455503724	05055455500002167
156-515	Medial Rotation Knee™ Left Tibial Insert Size 1, 18mm	46585	P090903020202	05055455503731	05055455500002167
156-521	Medial Rotation Knee™ Left Tibial Insert Size 2, 8mm	46585	P090903020202	05055455503748	05055455500002167
156-522	Medial Rotation Knee™ Left Tibial Insert Size 2, 10.5mm	46585	P090903020202	05055455503755	05055455500002167
156-523	Medial Rotation Knee™ Left Tibial Insert Size 2, 13mm	46585	P090903020202	05055455503762	05055455500002167
156-524	Medial Rotation Knee™ Left Tibial Insert Size 2, 15.5mm	46585	P090903020202	05055455503779	05055455500002167
156-525	Medial Rotation Knee™ Left Tibial Insert Size 2, 18mm	46585	P090903020202	05055455503786	05055455500002167

Catalogue Number	Description	GMDN Code	EMDN Code	UDI-DI	Basic-UDI-DI
156-531	Medial Rotation Knee™ Left Tibial Insert Size 3, 8mm	46585	P090903020202	05055455503793	05055455500002167
156-532	Medial Rotation Knee™ Left Tibial Insert Size 3, 10.5mm	46585	P090903020202	05055455503809	05055455500002167
156-533	Medial Rotation Knee™ Left Tibial Insert Size 3, 13mm	46585	P090903020202	05055455503816	05055455500002167
156-534	Medial Rotation Knee™ Left Tibial Insert Size 3, 15.5mm	46585	P090903020202	05055455503823	05055455500002167
156-535	Medial Rotation Knee™ Left Tibial Insert Size 3, 18mm	46585	P090903020202	05055455503830	05055455500002167
156-611	Medial Rotation Knee™ Right Tibial Insert Size 1, 8mm	46585	P090903020202	05055455503847	05055455500002167
156-612	Medial Rotation Knee™ Right Tibial Insert Size 1, 10.5mm	46585	P090903020202	05055455503854	05055455500002167
156-613	Medial Rotation Knee™ Right Tibial Insert Size 1, 13mm	46585	P090903020202	05055455503861	05055455500002167
156-614	Medial Rotation Knee™ Right Tibial Insert Size 1, 15.5mm	46585	P090903020202	05055455503878	05055455500002167
156-615	Medial Rotation Knee™ Right Tibial Insert Size 1, 18mm	46585	P090903020202	05055455503885	05055455500002167
156-621	Medial Rotation Knee™ Right Tibial Insert Size 2, 8mm	46585	P090903020202	05055455503892	05055455500002167
156-622	Medial Rotation Knee™ Right Tibial Insert Size 2, 10.5mm	46585	P090903020202	05055455503908	05055455500002167
156-623	Medial Rotation Knee™ Right Tibial Insert Size 2, 13mm	46585	P090903020202	05055455503915	05055455500002167
156-624	Medial Rotation Knee™ Right Tibial Insert Size 2, 15.5mm	46585	P090903020202	05055455503922	05055455500002167
156-625	Medial Rotation Knee™ Right Tibial Insert Size 2, 18mm	46585	P090903020202	05055455503939	05055455500002167



Catalogue Number	Description	GMDN Code	EMDN Code	UDI-DI	Basic-UDI-DI
156-631	Medial Rotation Knee™ Right Tibial Insert Size 3, 8mm	46585	P090903020202	05055455503946	05055455500002167
156-632	Medial Rotation Knee™ Right Tibial Insert Size 3, 10.5mm	46585	P090903020202	05055455503953	05055455500002167
156-633	Medial Rotation Knee™ Right Tibial Insert Size 3, 13mm	46585	P090903020202	05055455503960	05055455500002167
156-634	Medial Rotation Knee™ Right Tibial Insert Size 3, 15.5mm	46585	P090903020202	05055455503977	05055455500002167
156-635	Medial Rotation Knee™ Right Tibial Insert Size 3, 18mm	46585	P090903020202	05055455503984	05055455500002167
156-701	MRK™ All-Poly Tibia Left T1 10.5mm	33580	P09090302	05055455504028	05055455500001164
156-702	MRK™ All-Poly Tibia Left T1 13.0mm	33580	P09090302	05055455504035	05055455500001164
156-703	MRK™ All-Poly Tibia Left T1 15.5mm	33580	P09090302	05055455504042	05055455500001164
156-704	MRK™ All-Poly Tibia Left T1 18.0mm	33580	P09090302	05055455504059	05055455500001164
156-706	MRK™ All-Poly Tibia Left T2 10.5mm	33580	P09090302	05055455504066	05055455500001164
156-707	MRK™ All-Poly Tibia Left T2 13.0mm	33580	P09090302	05055455504073	05055455500001164
156-708	MRK™ All-Poly Tibia Left T2 15.5mm	33580	P09090302	05055455504080	05055455500001164
156-709	MRK™ All-Poly Tibia Left T2 18.0mm	33580	P09090302	05055455504097	05055455500001164
156-711	MRK™ All-Poly Tibia Left T3 10.5mm	33580	P09090302	05055455504103	05055455500001164
156-712	MRK™ All-Poly Tibia Left T3 13.0mm	33580	P09090302	05055455504110	05055455500001164
156-713	MRK™ All-Poly Tibia Left T3 15.5mm	33580	P09090302	05055455504127	05055455500001164
156-714	MRK™ All-Poly Tibia Left T3 18.0mm	33580	P09090302	05055455504134	05055455500001164
156-716	MRK™ All-Poly Tibia Left T4 10.5mm	33580	P09090302	05055455504141	05055455500001164
156-717	MRK™ All-Poly Tibia Left T4 13.0mm	33580	P09090302	05055455504158	05055455500001164
156-718	MRK™ All-Poly Tibia Left T4 15.5mm	33580	P09090302	05055455504165	05055455500001164

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156-719	MRK™ All-Poly Tibia Left T4 18.0mm	33580	P09090302	05055455504172	05055455500001164
156-721	MRK™ All-Poly Tibia Left T5 10.5mm	33580	P09090302	05055455504189	05055455500001164
156-722	MRK™ All-Poly Tibia Left T5 13.0mm	33580	P09090302	05055455504196	05055455500001164
156-723	MRK™ All-Poly Tibia Left T5 15.5mm	33580	P09090302	05055455504202	05055455500001164
156-724	MRK™ All-Poly Tibia Left T5 18.0mm	33580	P09090302	05055455504219	05055455500001164
156-726	MRK™ All-Poly Tibia Right T1 10.5mm	33580	P09090302	05055455504226	05055455500001164
156-727	MRK™ All-Poly Tibia Right T1 13.0mm	33580	P09090302	05055455504233	05055455500001164
156-728	MRK™ All-Poly Tibia Right T1 15.5mm	33580	P09090302	05055455504240	05055455500001164
156-729	MRK™ All-Poly Tibia Right T1 18.0mm	33580	P09090302	05055455504257	05055455500001164
156-731	MRK™ All-Poly Tibia Right T2 10.5mm	33580	P09090302	05055455504264	05055455500001164
156-732	MRK™ All-Poly Tibia Right T2 13.0mm	33580	P09090302	05055455504271	05055455500001164
156-733	MRK™ All-Poly Tibia Right T2 15.5mm	33580	P09090302	05055455504288	05055455500001164
156-734	MRK™ All-Poly Tibia Right T2 18.0mm	33580	P09090302	05055455504295	05055455500001164
156-736	MRK™ All-Poly Tibia Right T3 10.5mm	33580	P09090302	05055455504301	05055455500001164
156-737	MRK™ All-Poly Tibia Right T3 13.0mm	33580	P09090302	05055455504318	05055455500001164
156-738	MRK™ All-Poly Tibia Right T3 15.5mm	33580	P09090302	05055455504325	05055455500001164
156-739	MRK™ All-Poly Tibia Right T3 18.0mm	33580	P09090302	05055455504332	05055455500001164
156-741	MRK™ All-Poly Tibia Right T4 10.5mm	33580	P09090302	05055455504349	05055455500001164
156-742	MRK™ All-Poly Tibia Right T4 13.0mm	33580	P09090302	05055455504356	05055455500001164
156-743	MRK™ All-Poly Tibia Right T4 15.5mm	33580	P09090302	05055455504363	05055455500001164
156-744	MRK™ All-Poly Tibia Right T4 18.0mm	33580	P09090302	05055455504370	05055455500001164

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156-746	MRK™ All-Poly Tibia Right T5 10.5mm	33580	P09090302	05055455504387	05055455500001164
156-747	MRK™ All-Poly Tibia Right T5 13.0mm	33580	P09090302	05055455504394	05055455500001164
156-748	MRK™ All-Poly Tibia Right T5 15.5mm	33580	P09090302	05055455504400	05055455500001164
156-749	MRK™ All-Poly Tibia Right T5 18.0mm	33580	P09090302	05055455504417	05055455500001164
156-820	Medial Rotation Knee™ Patella 20mm	34199	P09099001	05055455504844	05055455500002065
156-825	Medial Rotation Knee™ Patella 25mm	34199	P09099001	05055455504851	05055455500002065
156-830	Medial Rotation Knee™ Patella 30mm	34199	P09099001	05055455504868	05055455500002065
156-920	Medial Rotation Knee™ Patella Reduced Thickness 20mm	34199	P09099001	05055455504875	05055455500002065
156-925	Medial Rotation Knee™ Patella Reduced Thickness 25mm	34199	P09099001	05055455504882	05055455500002065

If you require further information, please contact your usual representative in the first place or customer services on [customer.services@matortho.com](mailto:customer.services@matortho.com) +44 (0)1372 366300.

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