User Name
User Address Line 1
User Address Line 2
User Address Line 3

URGENT FIELD SAFETY NOTICE

Product Name:	PIPR™
Reference:	FSN-21-008
Action Type:	Field Safety Notice on Medical Device – Read updated IFU
Date:	18 October 2021
Device Type:	Finger Joint 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 phalangeal joints with arc of motion >20° pre- operatively where there is painful and disabled joint resulting from:
1. osteoarthritis, or
2. rheumatoid arthritis where one or more compartments are involved, and which may result in varus or valgus deformity.

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,

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,
9. pre-operatively stiff fingers with arc of motion <20°.

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/400-478.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

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.

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
186-022	PIPR™ Complete Joint P8, M7	60459	Y061803	05055455505711	0505545550000246D
186-023	PIPR™ Complete Joint P9, M8	60459	Y061803	05055455505728	0505545550000246D
186-024	PIPR™ Complete Joint P10, M9	60459	Y061803	05055455505735	0505545550000246D
186-025	PIPR™ Complete Joint P11, M10	60459	Y061803	05055455505742	0505545550000246D
186-031	PIPR™ Complete Joint Size 7	60459	Y061803	05055455505759	0505545550000246D
186-032	PIPR™ Complete Joint Size 8	60459	Y061803	05055455505766	0505545550000246D
186-033	PIPR™ Complete Joint Size 9	60459	Y061803	05055455505773	0505545550000246D
186-034	PIPR™ Complete Joint Size 10	60459	Y061803	05055455505780	0505545550000246D
186-035	PIPR™ Complete Joint Size 11	60459	Y061803	05055455505797	0505545550000246D

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

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MatOrtho Limited
19/20 Mole Business Park
Randalls Road
Leatherhead, Surrey, KT22 7BA

Field Safety Notice Distributor/Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN-21-008
FSN Date*	Pre-filled by manufacturer
Product/ Device name*	PIPR™ Finger Joint Replacement
Product Code(s)	See Attached FSN

2. Distributor/Importer Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Return acknowledgement to Sender	
Email	customer.services@matortho.com
Distributor/Importer Helpline	+44 (0)1372 366300
Postal Address	19/20 Mole Business Park Randalls Road Leatherhead, Surrey, KT22 7BA
Deadline for returning the Distributor/Importer reply form*	Pre-filled by manufacturer/sender/requester

4. Distributors/Importers (Tick all that apply)		
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A
☐	I have identified customers that received or may have received this device	
☐	I have attached customer list	

Forever Active

4. Distributors/Importers (Tick all that apply)		
☐	I have informed the identified customers of this FSN	Date of communication:
☐	I have received confirmation of reply from all identified customers	
Print Name*		Distributor/Importer print name here
Signature*		Distributor/Importer sign Here
Date *		

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

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