

## Re-Call Control Registry

Re: FSCA # 2021/003/010/601/004  
FSN # 2021/001/013/479/002

Document Ref #: 001

### Product Description and Brief History:

- ROTOglide MTP System
- This product has been on the market for some 20+ years and is widely regarded as the safest and best performing MTP system in the world.

### Background:

Information Safety Information TL/2021/05 dated 17.02.2021 and MHRA Targeted Letter dated 18.05.2021.

### Reason for FSN:

Following withdrawal of CE certification by BSI on 04.09.2019, due to a commercial dispute between Implants International Ltd and BSI. The withdrawal was not due to any product safety, efficacy or performance issues of the product.

### Affected Period:

September 4<sup>th</sup>, 2019 to date

### Target:

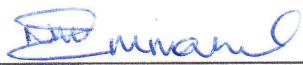
Track, review and risk analyse the product shipped and implanted in the affected period.

### Object and Time Scales:

- Recall all product held in Denmark as per attached excel sheet
- Product returned by 7<sup>th</sup> June, 2021

### Action:

Inform sub distributors of the background of this situation and also contact Surgeons/Hospitals who implanted ROTOglide between 04.09.2019 to date, and inform them of the need for monitoring/follow-up of patients affected for any adverse reactions and report any incidents through the National Healthcare Incident Reporting System, with a copy of such incidents sent to Implants International Ltd by email for consolidation.



N M Emmanuel  
Director of Operations

Date: 26 May 2021

MD 138 Rev. 0 May 2021

#### Registered Office:

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Company Registered in England • Registration Number 5467946

Udløbsdato	Varenumr	Varenavn	Lokatio	Serienumr	Antal
30/06/2020	GT5038	RotoGlide Metatarsal, anatomisk, M, Left Prot eser	1	IS7167	1
04/09/2020	GT5037	RotoGlide Metatarsal, anatomisk, S, Righ Prot eser	1	IS7242	2
09/01/2021	GT5018	RotoGlide Mob. Meniscus, std. 6mm, S Prot eser	1	IS6800	1
16/03/2021	GT5041	RotoGlide Metatarsal, anatomisk, L, Righ Prot eser	1	IS7248.	1
16/03/2021	GT5042	RotoGlide Neutral Phalangeal, S Prot eser	1	IS6881.	2
19/04/2021	GT5018	RotoGlide Mob. Meniscus, std. 6mm, S Prot eser	1	IS6800.	1
19/04/2021	GT5021	RotoGlide Mob. Meniscus, std. 7mm, S Prot eser	1	IS6799	1
19/04/2021	GT5050	RotoGlide Neutral Phalangeal, XL Prot eser	1	IS7294	2
08/05/2021	GT5040	RotoGlide Metatarsal, anatomisk, L, Left Prot eser	1	IS7297	2
07/12/2021	GT5022	RotoGlide Mob. Meniscus, std. 7mm, M Prot eser	1	IS7366	2
11/03/2024	GT5023	RotoGlide Mob. Meniscus, std. 7mm, L Prot eser	1	IS7568	3
31-01 2021	GT5021	RotoGlide Mob. Meniscus, std. 7mm, S Prot eser	1	IS7157	1
31-01 2021	GT5022	RotoGlide Mob. Meniscus, std. 7mm, M Prot eser	1	IS7161	1
11/03/2019	GT5020	RotoGlide Mob. Meniscus, std. 6mm, L	2005	IS7569	1
22/03/2022	GT5041	RotoGlide Metatarsal, anatomisk, L, Righ Prot eser	2005	IS7351	1
08/05/2021	GT5041	RotoGlide Metatarsal, anatomisk, L, Righ Prot eser	2005	IS7248	1
08/05/2021	GT5040	RotoGlide Metatarsal, anatomisk, L, Left Prot eser	2005	IS7297	1
16/03/2021	GT5037	RotoGlide Metatarsal, anatomisk, S, Righ Prot eser	2005	IS7242	1
26/11/2020	GT5036	RotoGlide Metatarsal, anatomisk, S, Left	2005	IS7247	1
26/11/2020	GT5020	RotoGlide Mob. Meniscus, std. 6mm, L	2005	IS7227	1
26/11/2020	GT5050	RotoGlide Neutral Phalangeal, XL Prot eser	2005	IS7156	1

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**Unsterile implants and Instruments**

19/11/2020	GT5039	ROTOglide Metatarsal Medium Right	IS7170	1
19/11/2020	GT5038	ROTOglide Metatarsal Medium Left	IS7166	1
19/11/2020	GT5038	ROTOglide Metatarsal Medium Left	IS7166	1
19/11/2020	GT5043	ROTOglide Neutral Phalanx Medium	IS7295	1
19/11/2020	GT5044	ROTOglide Neutral Phalanx Large	IS7291	1
19/11/2020	GT5044	ROTOglide Neutral Phalanx Large	IS7291	1
19/11/2020	GT5044	ROTOglide Neutral Phalanx Large	IS7291	1
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19/11/2020	IN9563	Dorsal Fixation Pin - Medium		1
19/11/2020	IN9562	Dorsal Fixation Pin - Short		1
19/11/2020	IN9562	Dorsal Fixation Pin - Short		1
19/11/2020	IN9564	Dorsal Fixation Pin - Long		1
19/11/2020	IN9564	Dorsal Fixation Pin - Long		1
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