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Summary of Safety and Clinical Performance

Replacements of a part of the upper limb - trapeziometacarpal joint replacement

back in motion

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Introduction

The purpose of this Summary of Safety and Clinical Performance (SSCP) is to provide public access to the updated summary of the key aspects of safety and clinical performance of the device.

The SSCP is not intended to replace the instructions for use, which are the main document intended for ensuring safe use of the device, or as a document providing diagnostic or therapeutical suggestions to intended users or patients.

The following information is intended for users/medical professionals.

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Date:

07/02/2023

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2

Language identification:

English

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1. Identification of MD and manufacturer

1.1 Trade names of MD

Number	Order no.	Trade name	UDI-DI code
1	413001	ELIS - DŘÍK NECEM., T, 1	8592602145422
		ELiS - Cementless stem, T, 1	
		ELiS - Zementfreier Schaft, T, 1	
		ELiS - Driek necem., T, 1	
		ELiS - Vástago sin cementar, T, 1	
		ELiS - Haste não ciment., T, 1	
		ELiS - Бесцементная ножка, T, 1	
		ELiS - Безцементна ніжка, T, 1	
2	413002	ELIS - DŘÍK NECEM., T, 2	8592602145439
		ELiS - Cementless stem, T, 2	
		ELiS - Zementfreier Schaft, T, 2	
		ELiS - Driek necem., T, 2	
		ELiS - Vástago sin cementar, T, 2	
		ELiS - Haste não ciment., T, 2	
		ELiS - Бесцементная ножка, T, 2	
		ELiS - Безцементна ніжка, T, 2	
3	413003	ELIS - DŘÍK NECEM., T, 3	8592602145446
		ELiS - Cementless stem, T, 3	
		ELiS - Zementfreier Schaft, T, 3	
		ELiS - Driek necem., T, 3	
		ELiS - Vástago sin cementar, T, 3	
		ELiS - Haste não ciment., T, 3	
		ELiS - Бесцементная ножка, T, 3	
		ELiS - Безцементна ніжка, T, 3	
4	413004	ELIS - DŘÍK NECEM., T, 4	8592602145453
		ELiS - Cementless stem, T, 4	
		ELiS - Zementfreier Schaft, T, 4	
		ELiS - Driek necem., T, 4	
		ELiS - Vástago sin cementar, T, 4	
		ELiS - Haste não ciment., T, 4	
		ELiS - Бесцементная ножка, T, 4	
		ELiS - Безцементна ніжка, T, 4	
5	413005	ELIS - DŘÍK NECEM., T, 5	8592602242503
		ELiS - Cementless stem, T, 5	
		ELiS - Zementfreier Schaft, T, 5	
		ELiS - Driek necem., T, 5	
		ELiS - Vástago sin cementar, T, 5	
		ELiS - Vástago sin cementar, T, 5	
		ELiS - Бесцементная ножка, T/II (Ti+ГА), 5	
		ELiS - Безцементна ніжка, T/II (Ti та ГА), 5	
6	413011	ELIS - DŘÍK NECEM., T/II (TI+HA), 1	8592602200466
		ELiS - Cementless stem, T/II (Ti+HA), 1	
		ELiS - Zementfreier Schaft, T/II (Ti+HA), 1	
		ELiS - Driek necem., T/II (Ti+HA), 1	

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		ELiS - Vástago sin cementar, T/II (Ti+HA), 1	
		ELiS - Haste não ciment., T/II (Ti + HA), 1	
		ELiS - Бесцементная ножка, T/II (Ti+ГА), 1	
		ELiS - Безцементна ніжка, T/II (Ti та ГА), 1	
7	413012	ELIS - DŘÍK NECEM., T/II (TI+HA), 2	8592602200473
		ELiS - Cementless stem, T/II (Ti+HA), 2	
		ELiS - Zementfreier Schaft, T/II (Ti+HA),	
		ELiS - Driek necem., T/II (Ti+HA), 2	
		ELiS - Vástago sin cementar, T/II (Ti+HA), 2	
		ELiS - Haste não ciment., T/II (Ti + HA), 2	
		ELiS - Бесцементная ножка, T/II (Ti+ГА), 2	
		ELiS - Безцементна ніжка, T/II (Ti та ГА), 2	
8	413013	ELIS - DŘÍK NECEM., T/II (TI+HA), 3	8592602200480
		ELiS - Cementless stem, T/II (Ti+HA), 3	
		ELiS - Zementfreier Schaft, T/II (Ti+HA), 3	
		ELiS - Driek necem., T/II (Ti+HA), 3	
		ELiS - Vástago sin cementar, T/II (Ti+HA), 3	
		ELiS - Haste não ciment., T/II (Ti + HA), 3	
		ELiS - Бесцементная ножка, T/II (Ti+ГА), 3	
		ELiS - Безцементна ніжка, T/II (Ti та ГА), 2	
9	413014	ELIS - DŘÍK NECEM., T/II (TI+HA), 4	8592602200497
		ELiS - Cementless stem, T/II (Ti+HA), 4	
		ELiS - Zementfreier Schaft, T/II (Ti+HA), 4	
		ELiS - Driek necem., T/II (Ti+HA), 4	
		ELiS - Vástago sin cementar, T/II (Ti+HA), 4	
		ELiS - Haste não ciment., T/II (Ti + HA), 4	
		ELiS - Бесцементная ножка, T/II (Ti+ГА), 4	
		ELiS - Безцементна ніжка, T/II (Ti та ГА), 4	
10	413015	ELIS - DŘÍK NECEM., T/II (TI+HA), 5	8592602200503
		ELiS - Cementless stem, T/II (Ti+HA), 5	
		ELiS - Zementfreier Schaft, T/II (Ti+HA), 5	
		ELiS - Driek necem., T/II (Ti+HA), 5	
		ELiS - Vástago sin cementar, T/II (Ti+HA), 5	
		ELiS - Haste não ciment., T/II (Ti + HA), 5	
		ELiS - Бесцементная ножка, T/II (Ti+ГА), 5	
		ELiS - Безцементна ніжка, T/II (Ti та ГА), 5	
11	413021	ELIS - DŘÍK NECEM. (KN), 1	8592602249519
		ELiS - Cementless stem, (CC), 1	
		ELiS - Zementfreier Schaft, (CC), 1	
		ELiS - Driek necem., (CC), 1	
		ELiS - Vástago sin cementar, (CC), 1	
		ELiS - Haste não ciment., (CC), 1	
		ELiS - Бесцементная ножка, (CC), 1	
		ELiS - Безцементна ніжка, (CC), 1	
12	413026	ELIS - DŘÍK NECEM. (KN), 1+	8592602249564
		ELiS - Cementless stem, (CC), 1+	
		ELiS - Zementfreier Schaft, (CC), 1+	
		ELiS - Driek necem., (CC), 1+	
		ELiS - Vástago sin cementar, (CC), 1+	
		ELiS - Haste não ciment., (CC), 1+	

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		ELiS - Бесцементная ножка, (CC), 1+	
		ELiS - Безцементна ніжка, (CC), 1+	
13	413022	ELIS - DŘÍK NECEM. (KN), 2	8592602249526
		ELiS - Cementless stem, (CC), 2	
		ELiS - Zementfreier Schaft, (CC), 2	
		ELiS - Driek necem., (CC), 2	
		ELiS - Vástago sin cementar, (CC), 2	
		ELiS - Haste não ciment., (CC), 2	
		ELiS - Бесцементная ножка, (CC), 2	
		ELiS - Безцементна ніжка, (CC), 2	
14	413027	ELIS - DŘÍK NECEM. (KN), 2+	8592602249571
		ELiS - Cementless stem, (CC), 2+	
		ELiS - Zementfreier Schaft, (CC), 2+	
		ELiS - Driek necem., (CC), 2+	
		ELiS - Vástago sin cementar, (CC), 2+	
		ELiS - Haste não ciment., (CC), 2+	
		ELiS - Бесцементная ножка, (CC), 2+	
		ELiS - Безцементна ніжка, (CC), 2+	
15	413023	ELIS - DŘÍK NECEM. (KN), 3	8592602249533
		ELiS - Cementless stem, (CC), 3	
		ELiS - Zementfreier Schaft, (CC), 3	
		ELiS - Driek necem., (CC), 3	
		ELiS - Haste não ciment., (CC), 3	
		ELiS - Бесцементная ножка, (CC), 3	
		ELiS - Безцементна ніжка, (CC), 3	
16	413024	ELIS - DŘÍK NECEM. (KN), 4	8592602249540
		ELiS - Cementless stem, (CC), 4	
		ELiS - Zementfreier Schaft, (CC), 4	
		ELiS - Driek necem., (CC), 4	
		ELiS - Vástago sin cementar, (CC), 4	
		ELiS - Haste não ciment., (CC), 4	
		ELiS - Безцементна ніжка, (CC), 4	
		ELiS — Безцементна ніжка, (CC), 4	
17	413025	ELIS - DŘÍK NECEM. (KN), 5	8592602249557
		ELiS - Cementless stem, (CC), 5	
		ELiS - Zementfreier Schaft, (CC), 5	
		ELiS - Driek necem., (CC), 5	
		ELiS - Vástago sin cementar, (CC), 5	
		ELiS - Haste não ciment., (CC), 5	
		ELiS - Бесцементная ножка, (CC), 5	
		ELiS - Безцементна ніжка, (CC), 5	
18	413028	ELIS - DŘÍK NECEM. (KN), 5+	8592602249588
		ELiS - Cementless stem, (CC), 5+	
		ELiS - Zementfreier Schaft, (CC), 5+	
		ELiS - Driek necem., (CC), 5+	
		ELiS - Vástago sin cementar, (CC), 5+	
		ELiS - Haste não ciment., (CC), 5+	
		ELiS - Бесцементная ножка, (CC), 5+	
		ELiS - Безцементна ніжка, (CC), 5	

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Number	Order no.	Trade name	UDI-DI code
19	413072	ELIS - KRČEK PŘÍMÝ, T/II, 5/12, S	8592602145460
		ELiS - Straight neck, T/II, 5/12, S	
		ELiS - Hals, gerade, T/II, 5/12, S	
		ELiS - Krčok priamy, T/II, 5/12, S	
		ELiS - Cuello recto, T/II, 5/12, S	
		ELiS - Colo reto, T/II, 5/12, S	
		ELiS - Прямая шейка, T/II, 5/12, S	
		ELiS - Пряма шийка, T/II, 5/12, S	
20	413073	ELIS - KRČEK PŘÍMÝ, T/II, 5/14, M	8592602145477
		ELiS - Straight neck, T/II, 5/14, M	
		ELiS - Hals, gerade, T/II, 5/14, M	
		ELiS - Krčok priamy, T/II, 5/14, M	
		ELiS - Cuello recto, T/II, 5/14, M	
		ELiS - Colo reto, T/II, 5/14, M	
		ELiS - Прямая шейка, T/II, 5/14, M	
		ELiS - Пряма шийка, T/II, 5/14, M	
21	413074	ELIS - KRČEK PŘÍMÝ, T/II, 5/16, L	8592602145484
		ELiS - Straight neck, T/II, 5/16, L	
		ELiS - Hals, gerade, T/II, 5/16, L	
		ELiS - Krčok priamy, T/II, 5/16, L	
		ELiS - Cuello recto, T/II, 5/16, L	
		ELiS - Colo reto, T/II, 5/16, L	
		ELiS - Прямая шейка, T/II, 5/16, L	
		ELiS - Пряма шийка, T/II, 5/16, L	
22	413075	ELIS - KRČEK PŘÍMÝ, T/II, 5/18, XL	8592602145491
		ELiS - Straight neck, T/II, 5/18, XL	
		ELiS - Hals, gerade, T/II, 5/18, XL	
		ELiS - Krčok priamy, T/II, 5/18, XL	
		ELiS - Cuello recto, T/II, 5/18, XL	
		ELiS - Colo reto, T/II, 5/18, XL	
		ELiS - Прямая шейка, T/II, 5/18, XL	
		ELiS - Пряма шийка, T/II, 5/18, XL	
23	413077	ELIS - KRČEK VALGÓZNÍ 15°, T/II, 5/12, S	8592602145507
		ELiS - Valgus neck 15°, T/II, 5/12, S	
		ELiS - Hals, Valgus 15°, T/II, 5/12, S	
		ELiS - Krčok valgózny 15°, T/II, 5/12, S	
		ELiS - Cuello recto, T/II, 5/18, XL	
		ELiS - Colo valgo 15°, T/II, 5/12, S	
		ELiS - Шейка вальгусная 15°, T/II, 5/12, S	
		ELiS - Шийка вальгусна 15°, T/II, 5/12, S	
24	413078	ELIS - KRČEK VALGÓZNÍ 15°, T/II, 5/14, M	8592602145514
		ELiS - Valgus neck 15°, T/II, 5/14, M	
		ELiS - Hals, Valgus 15°, T/II, 5/14, M	
		ELiS - Krčok valgózny 15°, T/II, 5/14, M	
		ELiS - Cuello valgus de 15°, T/II, 5/14, M	
		ELiS - Colo valgo 15°, T/II, 5/14, M	
		ELiS - Шейка вальгусная 15°, T/II, 5/14, M	
		ELiS - Шийка вальгусна 15°, T/II, 5/14, M	
25	413079	ELIS - KRČEK VALGÓZNÍ 15°, T/II, 5/16, L	8592602145521

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		ELiS - Valgus neck 15°, T/II, 5/16, L	
		ELiS - Hals, Valgus 15°, T/II, 5/16, L	
		ELiS - Krčok valgózny 15°, T/II, 5/16, L	
		ELiS - Cuello valgus de 15°, T/II, 5/16, M	
		ELiS - Colo valgo 15°, T/II, 5/16, L	
		ELiS - Шейка вальгусная 15°, T/II, 5/16, L	
		ELiS - Шийка вальгусна 15°, T/II, 5/16, L	
26	413080	ELIS - KRČEK VALGÓZNÍ 15°, T/II, 5/18, XL	8592602145538
		ELiS - Valgus neck 15°, T/II, 5/18, XL	
		ELiS - Hals, Valgus 15°, T/II, 5/18, XL	
		ELiS - Krčok valgózny 15°, T/II, 5/18, XL	
		ELiS - Cuello valgus de 15°, T/II, 5/18, XL	
		ELiS - Colo valgo 15°, T/II, 5/18, XL	
		ELiS - Шейка вальгусная 15°, T/II, 5/18, XL	
		ELiS - Шийка вальгусна 15°, T/II, 5/18, XL	
27	413087	ELIS - KRČEK VALG. 15°/ANTE-R, 5/12	8592602145545
		ELiS - Valgus neck 15°/Ante-R, 5/12	
		ELiS - Hals, Valgus 15°/Ante-R, 5/12	
		ELiS - Krčok valgózny 15°/Ante-R, 5/12	
		ELiS - Colo valgo 15°/Ante-R, 5/12	
		ELiS - Colo valgo 15°/Ante-R, 5/12	
		ELiS - Шейка вальгусная 15°/Ante-R, 5/12	
		ELiS - Шийка вальгусна 15°/Ante-R, 5/12	
28	413088	ELIS - KRČEK VALG. 15°/ANTE-R, 5/14	8592602249755
		ELiS - Valgus neck 15°/Ante-R, 5/14	
		ELiS - Hals, Valgus 15°/Ante-R, 5/14	
		ELiS - Krčok valgózny 15°/Ante-R, 5/14	
		ELiS - Cuello valgus de 15°/Ante-R, 5/14	
		ELiS - Colo valgo 15°/Ante-R, 5/14	
		ELiS - Шейка вальгусная 15°/Ante-R, 5/14	
		ELiS - Шийка вальгусна 15°/Ante-R, 5/14	
29	413089	ELIS - KRČEK VALG. 15°/ANTE-R, 5/16	8592602249762
		ELiS - Valgus neck 15°/Ante-R, 5/16	
		ELiS - Hals, Valgus 15°/Ante-R, 5/16	
		ELiS - Krčok valgózny 15°/Ante-R, 5/16	
		ELiS - Cuello valgus de 15°/Ante-L, 5/16	
		ELiS - Colo valgo 15°/Ante-L, 5/16	
		ELiS - Шейка вальгусная 15°/Ante-R, 5/16	
		ELiS - Шейка вальгусная 15°/Ante-R, 5/16	
30	413090	ELIS - KRČEK VALG. 15°/ANTE-R, 5/18	8592602249779
		ELiS - Valgus neck 15°/Ante-R, 5/18	
		ELiS - Hals, Valgus 15°/Ante-R, 5/18	
		ELiS - Krčok valgózny 15°/Ante-R, 5/18	
		ELiS - Cuello valgus de 15°/Ante-R, 5/18	
		ELiS - Colo valgo 15°/Ante-R, 5/18	
		ELiS - Шейка вальгусная 15°/Ante-R, 5/18	
		ELiS - Шийка вальгусна 15°/Ante-R, 5/18	
31	413097	ELIS - KRČEK VALG. 15°/ANTE-L, 5/12	8592602249786
		ELiS - Valgus neck 15°/Ante-L, 5/12	
		ELiS - Hals, Valgus 15°/Ante-L, 5/12	

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		ELiS - Krčok valgózny 15°/Ante-L, 5/12	
		ELiS - Cuello valgus de 15°/Ante-L, 5/12	
		ELiS - Colo valgo 15°/Ante-L, 5/12	
		ELiS - Шейка вальгусная 15°/Ante-L, 5/12	
		ELiS - Шийка вальгусна 15°/Ante-L, 5/12	
32	413098	ELIS - KRČEK VALG. 15°/ANTE-L, 5/14	8592602249410
		ELiS - Valgus neck 15°/Ante-L, 5/14	
		ELiS - Krčok valgózny 15°/Ante-L, 5/14	
		ELiS - Hals, Valgus 15°/Ante-L, 5/14	
		ELiS - Cuello valgus de 15°/Ante-L, 5/14	
		ELiS - Colo valgo 15°/Ante-L, 5/14	
		ELiS - Шейка вальгусная 15°/Ante-L, 5/14	
		ELiS - Шийка вальгусна 15°/Ante-L, 5/14	
33	413099	ELIS - KRČEK VALG. 15°/ANTE-L, 5/16	8592602249793
		ELiS - Valgus neck 15°/Ante-L, 5/16	
		ELiS - Hals, Valgus 15°/Ante-L, 5/16	
		ELiS - Krčok valgózny 15°/Ante-L, 5/16	
		ELiS - Cuello valgus de 15°/Ante-L, 5/16	
		ELiS - Colo valgo 15°/Ante-L, 5/16	
		ELiS - Шейка вальгусная 15°/Ante-L, 5/16	
		ELiS - Шийка вальгусна 15°/Ante-L, 5/16	
34	413100	ELIS - KRČEK VALG. 15°/ANTE-L, 5/18	8592602249809
		ELiS - Valgus neck 15°/Ante-L, 5/18	
		ELiS - Hals, Valgus 15°/Ante-L, 5/18	
		ELiS - Krčok valgózny 15°/Ante-L, 5/18	
		ELiS - Cuello valgus de 15°/Ante-L, 5/18	
		ELiS - Colo valgo 15°/Ante-L, 5/18	
		ELiS - Шейка вальгусная 15°/Ante-L, 5/18	
		ELiS - Шийка вальгусна 15°/Ante-L, 5/18	

Number	Order no.	Trade name	UDI-DI code
35	413062	ELIS - DM - KRČEK PŘÍMÝ, 7.7/12	8592602249595
		ELiS - DM - Straight neck, 7.7/12	
		ELiS - DM - Hals, gerade, 7.7/12	
		ELiS - DM - Krčok priamy, 7.7/12	
		ELiS - DM - Cuello recto, 7.7/12	
		ELiS - DM - Cuello recto, 7.7/12	
		ELiS - DM - Cuello recto, 7.7/12	
		ELiS - DM - Пряма шийка, 7.7/12	
36	413063	ELIS - DM - KRČEK PŘÍMÝ, 7.7/14	8592602249601
		ELiS - DM - Straight neck, 7.7/14	
		ELiS - DM - Hals, gerade, 7.7/14	
		ELiS - DM - Krčok priamy, 7.7/14	
		ELiS - DM - Cuello valgus de 15°, 7.7/14	
		ELiS - DM - Colo reto, 7.7/14	
		ELiS - DM - Прямая шейка, 7.7/14	
		ELiS - DM - Пряма шийка, 7.7/14	
37	413064	ELIS - DM - KRČEK PŘÍMÝ, 7.7/16	8592602249618
		ELiS - DM - Straight neck, 7.7/16	
		ELiS - DM - Hals, gerade, 7.7/16	

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		ELiS - DM - Krčok priamy, 7.7/16	
		ELiS - DM - Cuello valgus de 15°, 7.7/16	
		ELiS - DM - Colo reto, 7.7/16	
		ELiS - DM - Прямая шейка, 7.7/16	
		ELiS - DM - Пряма шийка, 7.7/16	
38	413065	ELIS - DM - KRČEK PŘÍMÝ, 7.7/18	8592602249625
		ELiS - DM - Straight neck, 7.7/18	
		ELiS - DM - Hals, gerade, 7.7/18	
		ELiS - DM - Krčok priamy, 7.7/18	
		ELiS - DM - Cuello valgus de 15°, 7.7/18	
		ELiS - DM - Colo reto, 7.7/18	
		ELiS - DM - Прямая шейка, 7.7/18	
		ELiS - DM - Пряма шийка, 7.7/18	
39	413067	ELIS - DM - KRČEK VALG. 15°, 7.7/12	8592602249632
		ELiS - DM - Valgus neck 15°, 7.7/12	
		ELiS - DM - Hals, Valgus 15°, 7.7/12	
		ELiS - DM - Krčok valgózny 15°, 7.7/12	
		ELiS - DM - Cuello valgus de 15°, 7.7/12	
		ELiS - DM - Cuello valgus de 15°, 7.7/12	
		ELiS - DM — Шейка вальгусная 15°, 7.7/12	
		ELiS - DM — Шийка вальгусна 15°, 7.7/12	
40	413068	ELIS - DM - KRČEK VALG. 15°, 7.7/14	8592602249649
		ELiS - DM - Hals, Valgus 15°, 7.7/14	
		ELiS - DM - Krčok valgózny 15°, 7.7/14	
		ELiS - DM - Cuello valgus de 15°, 7.7/14	
		ELiS - DM - Cuello valgus de 15°, 7.7/14	
		ELiS – DM - Шейка вальгусная 15°, 7.7/14	
		ELiS - DM - Шийка вальгусна 15°, 7.7/14	
		ELiS - DM - Hals, Valgus 15°, 7.7/14	
41	413069	ELIS - DM - KRČEK VALG. 15°, 7.7/16	8592602249656
		ELiS - DM - Hals, Valgus 15°, 7.7/16	
		ELiS - DM - Krčok valgózny 15°, 7.7/16	
		ELiS - DM - Cuello valgus de 15°, 7.7/16	
		ELiS - DM - Cuello valgus de 15°, 7.7/16	
		ELiS - DM - Шейка вальгусная 15°, 7.7/16	
		ELiS - DM - Шийка вальгусна 15°, 7.7/16	
		ELiS - DM - Hals, Valgus 15°, 7.7/16	
42	413070	ELIS - DM - KRČEK VALG. 15°, 7.7/18	8592602249663
		ELiS - DM - Hals, Valgus 15°, 7.7/18	
		ELiS - DM - Krčok valgózny 15°, 7.7/18	
		ELiS - DM - Cuello valgus de 15°, 7.7/18	
		ELiS - DM - Cuello valgus de 15°, 7.7/18	
		ELiS - DM - Шейка вальгусная 15°, 7.7/18	
		ELiS - DM - Шийка вальгусна 15°, 7.7/18	
		ELiS - DM - Hals, Valgus 15°, 7.7/18	
43	413054	ELIS - DM - KRČEK VALG. 15°/ANTE-L, 7.7/12	8592602249670
		ELiS - DM - Valgus neck 15°/Ante-L, 7.7/12	
		ELiS - DM - Hals, Valgus 15°/Ante-L, 7.7/12	
		ELiS - DM - Krčok valgózny 15°/Ante-L, 7.7/12	
		ELiS - DM - Cuello valgus de 15°/Ante-L, 7.7/12	

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		ELiS - DM - Cuello valgus de 15°/Ante-L, 7.7/12	
		ELiS - DM - Шейка вальгусная 15°/Ante-L, 7.7/12	
		ELiS - DM - Шийка вальгусна 15°/Ante-L, 7.7/12	
44	413055	ELIS - DM - KRČEK VALG. 15°/ANTE-L, 7.7/14	8592602249687
		ELiS - DM - Valgus neck 15°/Ante-L, 7.7/14	
		ELiS - DM - Hals, Valgus 15°/Ante-L, 7.7/14	
		ELiS - DM - Krčok valgózny 15°/Ante-L, 7.7/14	
		ELiS - DM - Cuello valgus de 15°/Ante-L, 7.7/14	
		ELiS - DM - Cuello valgus de 15°/Ante-L, 7.7/14	
		ELiS - DM - Шейка вальгусная 15°/Ante-L, 7.7/14	
		ELiS - DM - Шийка вальгусна 15°/Ante-L, 7.7/14	
45	413056	ELIS - DM - KRČEK VALG. 15°/ANTE-L, 7.7/16	8592602249694
		ELiS - DM - Valgus neck 15°/Ante-L, 7.7/16	
		ELiS - DM - Hals, Valgus 15°/Ante-L, 7.7/16	
		ELiS - DM - Krčok valgózny 15°/Ante-L, 7.7/16	
		ELiS - DM - Cuello valgus de 15°/Ante-L, 7.7/16	
		ELiS - DM - Cuello valgus de 15°/Ante-L, 7.7/16	
		ELiS - DM - Шейка вальгусная 15°/Ante-L, 7.7/16	
		ELiS - DM - Шийка вальгусна 15°/Ante-L, 7.7/16	
46	413057	ELIS - DM - KRČEK VALG. 15°/ANTE-L, 7.7/18	8592602249700
		ELiS - DM - Valgus neck 15°/Ante-L, 7.7/18	
		ELiS - DM - Hals, Valgus 15°/Ante-L, 7.7/18	
		ELiS - DM - Krčok valgózny 15°/Ante-L, 7.7/18	
		ELiS - DM - Cuello valgus de 15°/Ante-L, 7.7/18	
		ELiS - DM - Cuello valgus de 15°/Ante-L, 7.7/18	
		ELiS - DM - Шейка вальгусная 15°/Ante-L, 7.7/18	
		ELiS - DM - Шийка вальгусна 15°/Ante-L, 7.7/18	
47	413058	ELIS - DM - KRČEK VALG. 15°/ANTE-R, 7.7/12	8592602249717
		ELiS - DM - Valgus neck 15°/Ante-R, 7.7/12	
		ELiS - DM - Hals, Valgus 15°/Ante-R, 7.7/12	
		ELiS - DM - Krčok valgózny 15°/Ante-R, 7.7/12	
		ELiS - DM - Cuello valgus de 15°/Ante-R, 7.7/12	
		ELiS - DM - Cuello valgus de 15°/Ante-R, 7.7/12	
		ELiS - DM - Шейка вальгусная 15°/Ante-R, 7.7/12	
		ELiS - DM - Шийка вальгусна 15°/Ante-R, 7.7/12	
48	413059	ELIS - DM - KRČEK VALG. 15°/ANTE-R, 7.7/14	8592602249724
		ELiS - DM - Valgus neck 15°/Ante-R, 7.7/14	
		ELiS - DM - Hals, Valgus 15°/Ante-R, 7.7/14	
		ELiS - DM - Krčok valgózny 15°/Ante-R, 7.7/14	
		ELiS - DM - Cuello valgus de 15°/Ante-R, 7.7/14	
		ELiS - DM - Cuello valgus de 15°/Ante-R, 7.7/14	
		ELiS - DM - Шейка вальгусная 15°/Ante-R, 7.7/14	
		ELiS - DM - Шийка вальгусна 15°/Ante-R, 7.7/14	
49	413060	ELIS - DM - KRČEK VALG. 15°/ANTE-R, 7.7/16	8592602249731
		ELiS - DM - Valgus neck 15°/Ante-R, 7.7/16	
		ELiS - DM - Hals, Valgus 15°/Ante-R, 7.7/16	
		ELiS - DM - Krčok valgózny 15°/Ante-R, 7.7/16	
		ELiS - DM - Cuello valgus de 15°/Ante-R, 7.7/16	
		ELiS - DM - Cuello valgus de 15°/Ante-R, 7.7/16	
		ELiS - DM - Шейка вальгусная 15°/Ante-R, 7.7/16	

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		ELiS - DM - Шийка вальгусна 15°/Ante-R, 7.7/16	
50	413061	ELIS - DM - KRČEK VALG. 15°/ANTE-R, 7.7/18	8592602249748
		ELiS - DM - Valgus neck 15°/Ante-R, 7.7/18	
		ELiS - DM - Hals, Valgus 15°/Ante-R, 7.7/18	
		ELiS - DM - Krčok valgózny 15°/Ante-R, 7.7/18	
		ELiS - DM - Cuello valgus de 15°/Ante-R, 7.7/18	
		ELiS - DM - Cuello valgus de 15°/Ante-R, 7.7/18	
		ELiS - DM - Шейка вальгусная 15°/Ante-R, 7.7/18	
		ELiS - DM - Шейка вальгусная 15°/Ante-R, 7.7/18	

Number	Order no.	Trade name	UDI-DI code
51	413171	ELIS - PLÁŠŤ JAMKY NECEM., T/III, D9	8592602200596
		ELiS - Cementless cup, T/III, D9	
		ELiS - Zementfreie Pfanne, T/III, D9	
		ELiS - Plášť jamky necem., T/III, D9	
		ELiS - Cotilo sin cemento, T/III, D9	
		ELiS - Taça não ciment., T/III, D9	
		ELiS - Бесцементная чашка, T/III, D9	
		ELiS - Безцементна чашка, T/III, D9	
52	413172	ELIS - PLÁŠŤ JAMKY NECEM., T/III, D10	8592602200602
		ELiS - Cementless cup, T/III, D10	
		ELiS - Zementfreie Pfanne, T/III, D10	
		ELiS - Plášť jamky necem., T/III, D10	
		ELiS - Cotilo sin cemento, T/III, D10	
		ELiS - Taça não ciment., T/III, D10	
		ELiS - Бесцементная чашка, T/III, D10	
		ELiS - Безцементна чашка, T/III, D10	

Number	Order no.	Trade name	UDI-DI code
53	413173	ELIS - SPHERE - PLÁŠŤ JAMKY NECEM. (KN), D9	8592602249465
		ELiS - Sphere - Cementless cup (CC), D9	
		ELiS - Sphere - Zementfreie Pfanne (CC), D9	
		ELiS - Sphere - Plášť jamky necem. (CC), D9	
		ELiS - Sphere - Cotilo sin cemento (CC), D9	
		ELiS - Sphere - Taça não ciment. (CC), D9	
		ELiS - Sphere - Бесцементная чашка (CC), D9	
		ELiS - Sphere - Безцементна чашка (CC), D9	
54	413174	ELIS - SPHERE - PLÁŠŤ JAMKY NECEM. (KN), D10	8592602249472
		ELiS - Sphere - Cementless cup (CC), D10	
		ELiS - Sphere - Zementfreie Pfanne (CC), D10	
		ELiS - Sphere - Plášť jamky necem. (CC), D10	
		ELiS - Sphere - Cotilo sin cemento (CC), D10	
		ELiS - Sphere - Taça não ciment. (CC), D10	
		ELiS - Sphere - Бесцементная чашка (CC), D10	
		ELiS - Sphere - Безцементна чашка (CC), D10	
55	413175	ELIS - VLOŽKA, T/III, PRO HLAVIČKU D5	8592602200619
		ELiS - Insert, T/III, for head D5	
		ELiS - Einsatz, T/III, für Kopf D5	
		ELiS - Vložka, T/III, na hlavičku D5	
		ELiS - Inserto, T/III, para cabeza D5	

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		ELiS - Inserção, T/III, p/ cabeça D5	
		ELiS - Вставка, T/III, под головку D5	
		ELiS - Вставка, T/III, для головки D5	
56	413176	ELIS - SPHERE, DM - PLÁŠŤ JAMKY NECEM. (KN), D9	8592602249441
		ELiS - Sphere, DM - Cementless cup (CC), D9	
		ELiS - Sphere, DM - Zementfreie Pfanne (CC), D9	
		ELiS - Sphere, DM - Plášť jamky necem. (CC), D9	
		ELiS - Sphere, DM - Cotilo sin cemento (CC), D9	
		ELiS - Sphere, DM - Taça não ciment. (CC), D9	
		ELiS - Sphere, DM - Бесцементная чашка (CC), D9	
		ELiS - Sphere, DM - Безцементна чашка (CC), D9	
57	413177	ELIS - SPHERE, DM - PLÁŠŤ JAMKY NECEM. (KN), D10	8592602249458
		ELiS - Sphere, DM - Cementless cup (CC), D10	
		ELiS - Sphere, DM - Zementfreie Pfanne (CC), D10	
		ELiS - Sphere, DM - Plášť jamky necem. (CC), D10	
		ELiS - Sphere, DM - Cotilo sin cemento (CC), D10	
		ELiS - Sphere, DM - Taça não ciment. (CC), D10	
		ELiS - Sphere, DM - Бесцементная чашка (CC), D10	
		ELiS - Sphere, DM - Безцементна чашка (CC), D10	
58	413178	ELIS - KONOS, DM - PLÁŠŤ JAMKY NECEM. (KN), D9	8592602249427
		ELiS - Konos, DM - Cementless cup (CC), D9	
		ELiS - Konos, DM - Zementfreie Pfanne (CC), D9	
		ELiS - Konos, DM - Plášť jamky necem. (CC), D9	
		ELiS - Konos, DM - Cotilo sin cemento (CC), D9	
		ELiS - Konos, DM - Taça não ciment. (CC), D9	
		ELiS - Konos, DM - Бесцементная чашка (CC), D9	
		ELiS - Konos, DM - Безцементна чашка (CC), D9	
59	413179	ELIS - KONOS, DM - PLÁŠŤ JAMKY NECEM. (KN), D10	8592602249434
		ELiS - Konos, DM - Cementless cup (CC), D10	
		ELiS - Konos, DM - Zementfreie Pfanne (CC), D10	
		ELiS - Konos, DM - Plášť jamky necem. (CC), D10	
		ELiS - Konos, DM - Cotilo sin cemento (CC), D10	
		ELiS - Konos, DM - Taça não ciment. (CC), D10	
		ELiS - Konos, DM - Бесцементная чашка (CC), D10	
		ELiS - Konos, DM - Безцементна чашка (CC), D10	

Number	Order no.	Trade name	UDI-DI code
60	413082	ELIS - JAMKA CEM. S OFFSETEM, T/II, 5/10	8592602200640
		ELiS - Trapezium repl., TR, 16/17, D11	
		ELiS - Trapeziumersatz, TR, 16/17, D11	
		ELiS - Náhrada trapézia, TR, 16/17, D11	
		ELiS - Reemplazo de trapecio, TR, 16/17, D11	
		ELiS - Repl. de trapézio, TR, 16/17, D11	
		ELiS - Протез кости-трапеции, TR, 16/17, D11	
		ELiS - Протез кістки-трапеції, TR, 16/17, D11	
61	413092	ELIS - SPHERE - JAMKA CEM., 5/10	8592602249410
		ELiS - Sphere - Cemented cup, 5/10	
		ELiS - Sphere - Zementierte Pfanne, 5/10	
		ELiS - Sphere - Jamka cem., 5/10	
		ELiS - Sphere - Jamka cem., 5/10	

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		ELiS - Sphere - Taça ciment., 5/10	
		ELiS - Sphere - Цементная чашка, 5/10	
		ELiS - Sphere - Цементна чашка, 5/10	

Number	Order no.	Trade name	UDI-DI code
62	413180	ELIS - NÁHRADA TRAPÉZIA, TR, 14/15, D9	8592602200626
		ELiS - Trapezium repl., TR, 14/15, D9	
		ELiS - Trapeziumersatz, TR, 14/15, D9	
		ELiS - Náhrada trapézia, TR, 14/15, D9	
		ELiS - Reemplazo de trapecio, TR, 14/15, D9	
		ELiS - Repl. de trapézio, TR, 14/15, D9	
		ELiS - Протез кости-трапеции, TR, 14/15, D9	
		ELiS - Протез кістки-трапеції, TR, 14/15, D9	
63	413181	ELIS - NÁHRADA TRAPÉZIA, TR, 15/16, D10	8592602200633
		ELiS - Trapezium repl., TR, 15/16, D10	
		ELiS - Trapeziumersatz, TR, 15/16, D10	
		ELiS - Náhrada trapézia, TR, 15/16, D10	
		ELiS - Reemplazo de trapecio, TR, 15/16, D10	
		ELiS - Repl. de trapézio, TR, 15/16, D10	
		ELiS - Протез кости-трапеции, TR, 15/16, D10	
		ELiS - Протез кістки-трапеції, TR, 15/16, D10	
64	413182	ELIS - NÁHRADA TRAPÉZIA, TR, 16/17, D11	8592602200640
		ELiS - Trapezium repl., TR, 16/17, D11	
		ELiS - Trapeziumersatz, TR, 16/17, D11	
		ELiS - Náhrada trapézia, TR, 16/17, D11	
		ELiS - Reemplazo de trapecio, TR, 16/17, D11	
		ELiS - Repl. de trapézio, TR, 16/17, D11	
		ELiS - Протез кости-трапеции, TR, 16/17, D11	
		ELiS - Протез кістки-трапеції, TR, 16/17, D11	

Number	Order no.	Trade name	UDI-DI code
65	413190	ELIS - VLOŽKA NÁHR. TRAPÉZIA, TR, 9/5	8592602242510
		ELiS - Trapezium insert, TR, 9/5	
		ELiS - Trapeziumeinsatz, TR, 9/5	
		ELiS - Vložka náhr. trapézia, TR, 9/5	
		ELiS - Inserto de trapecio, TR, 9/5	
		ELiS - Inserção de trapézio, TR, 9/5	
		ELiS - Вставка для кости-трапеции, TR, 9/5	
		ELiS - Вставка для кістки-трапеції, TR, 9/5	
66	413191	ELIS - VLOŽKA NÁHR. TRAPÉZIA, TR, 10/5	8592602200657
		ELiS - Trapezium insert, TR, 10/5	
		ELiS - Trapeziumeinsatz, TR, 10/5	
		ELiS - Vložka náhr. trapézia, TR, 10/5	
		ELiS - Inserto de trapecio, TR, 10/5	
		ELiS - Inserção de trapézio, TR, 10/5	
		ELiS - Вставка для кости-трапеции, TR, 10/5	
		ELiS - Вставка для кістки-трапеції, TR, 10/5	
67	413192	ELIS - VLOŽKA NÁHR. TRAPÉZIA, TR, 11/5	8592602200664
		ELiS - Trapezium insert, TR, 11/5	
		ELiS - Trapeziumeinsatz, TR, 11/5	

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		ELiS - Vložka náhr. trapézia, TR, 11/5	
		ELiS - Inserto de trapecio, TR, 11/5	
		ELiS - Inserção de trapézio, TR, 11/5	
		ELiS - Вставка для кости-трапеции, TR, 11/5	
		ELiS - Вставка для кістки-трапеції, TR, 11/5	

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1.2 SRN (manufacturer's single registration number)

- CZ-MF-000000543

1.3 Basic UDI-DI

- 859260207001FZ

1.4 MD nomenclature description/text

- P090404

1.5 MD class

- III

1.6 Year when the first certificate (CE) was issued covering the MD

- 2012 - DNV - Certificate No. 24538
- 2015 - EZÚ - MED 150068
- 2019 - EZÚ - MED 190044
- 2020 - EZÚ - MED 200056

1.7 Authorised representative, if applicable; name and SRN

- N/A

1.8 Notified body's name

- 3EC International a.s.
- Single registration number: 2265

2. Intended purpose of the device and any indications, contraindications and target populations

2.1 Intended purpose:

- The implants are intended as a replacement of the trapeziometacarpal joint.

2.2 Indications

Users are physicians meeting the following criteria:

- Physician (orthopaedist, traumatologist, surgeon)
- Must have experience with implantation of the trapeziometacarpal joint

Target group:

- Age – adult population 18+, men, women;
- Nationality – irrelevant;

Medical condition(s) (indications):

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- Primary and secondary rhizarthrosis resistant to conservative treatment; rheumatoid arthritis is relative indication (not applicable to the trapezium bone replacement); X-ray criterion Eaton-Littler II-IV; unfixed Z deformity of the thumb in the MCP joint.

2.3 Contraindications:

- Young, highly active patient (growth in progress);
- X-ray Eaton-Littler IV (not applicable to the trapezium bone replacement);
- Rigid Z deformity of the thumb in the MCP joint is relative contraindication (can be resolved at two time points or simultaneously with TEP of the TMC joint;
- Small trapezium bone (not applicable to the trapezium bone replacement);
- Dysplastic trapezium (Kapandji>140°) (not applicable to the trapezium bone replacement);
- Severe osteoporosis;
- Allergies (Ti, Al, V, Co, Cr, Mo, UHMWPE, HAp, bone cement);
- Specific and non-specific inflammatory disease;
- Tumours in the relevant location;
- Patient's inability to cooperate following the surgery.

3. Description of MD

3.1 Description:

- **Replacement of the trapeziometacarpal joint (TEP of the TMC joint)** consisting of a stem, neck and cup is intended for primo implantation in the case of damaged articulating parts of the trapezium and metacarpal bones that can no longer be addressed by conservative treatment. In special cases, the implant can also be used for revision surgery after a TEP failure.
  This configuration of the trapeziometacarpal joint replacement always consists of three parts – a metacarpal stem, neck with a head, and cementless cup placed in the trapezium bone (cup + PE insert) or a cemented cup.
  The total replacement of the trapeziometacarpal joint consisting of a stem, neck and trapezium replacement is intended for revision surgery, when the cup cannot be anchored in the trapezium due to the existing defects. Furthermore, it is intended for severe arthrosis Eaton–Littler IV requiring trapezium excision.
  This configuration of the trapeziometacarpal joint replacement always consists of three parts – a metacarpal stem, neck with a head with a diameter of 5 (mm) and trapezium replacement (body + PE insert).

- **ELiS – Cementless stem, T, T/II (Ti+HA) and ELiS – Cementless stem (CC)**
  Cementless stem is designed to fit the metacarpus medullary cavity with its shape and dimensions. The stem body is slightly curved and has a triangular cross section with rounded edges. The cone-shaped opening with an oval countersinking is provided in the upper part for inserting and fixing the neck to ensure anti-rotational stability of the neck. An M3 thread for the extractor is below the cone bottom. The stem is made of wrought titanium alloy Ti6Al4V (ISO 5832-3). The external surface is covered with Ti plasma coating (ISO 5832-2) in the upper part (ELiS type T – fig. 01),

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a double layer Ti + HA (ISO 5832-2 + ISO 13779-2) (ELiS type T/II – fig. 02) or a composite coating Ti layer with HA (ISO 5832-2 with ISO 13779-2) (ELiS type (CC) – fig. 03). The lower end of the stem is gently blasted in approximately 1/3 of its length. The stems are intended for configurations with all neck types.

Fig. 01 - ELiS - Cementless stem - type T

Fig. 02 - ELiS - Cementless stem - type T/II (Ti+HA)

Fig. 03 - ELiS - Cementless stem (CC)

- **ELiS – Neck TEP – type T/ II and ELiS – Straight neck, valgus, valgus/ante**

The neck (ELiS) is supplied in the straight (fig. 04) and valgus 15° version (fig. 05). The neck (ELiS) in the 15° valgus version is also supplied with right and left anteversion. These differ in the position of the neck axis against the axis of the connecting conical opening in the stem. Each of the versions comes in four different lengths (12, 14, 16 and 18 mm). The head diameter is 5 mm. All types and versions are made of wrought cobalt chromium molybdenum alloy (ISO 5832-12). The surface is brushed, except for the polished head surface.

Fig. 04 - ELiS - Straight neck

Fig. 05 - ELiS - Valgus neck

- **ELiS – DM – Neck**

The neck is supplied in the straight (fig. 06), 15° valgus (fig. 07) and 15° valgus version with right and left anteversion (fig. 08). They differ in the position of the neck axis similarly to the ELIS necks specified above. Each of the versions also comes in four different lengths (12, 14, 16 and 18 mm). A PE insert included as part of the neck is fitted on the articulating head with the diameter of 5 mm. The outer spherical surface of the PE insert is designed for articulation with the inner spherical surface of the ELiS – DM – Sphere or Konos cup. The neck is made of wrought cobalt chromium molybdenum alloy (ISO 5832-12). The neck

surface except for the polished head surface is brushed. The PE neck insert is made of ultra-high molecular weight polyethylene (ISO 5834-2).

Fig. 06 - ELiS – DM - Straight neck

Fig. 07 - ELiS - DM - Valgus neck

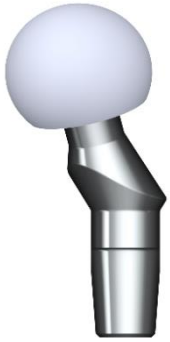

Fig. 08 - ELiS - DM - Valgus neck/ante

- **ELiS –Cementless cup – type T/ II and ELiS – Sphere – Cup**

Both cups consist of two separate MDs (the cup and PE insert). They are designed for affixing in the carpal bone at the base of the thumb (the trapezium bone) without using bone cement.

- **The cementless cup** has a spherical shape with the diameter of 9 or 10 mm. The outer surface includes anti-rotational elements along its circumference in the upper part (in the greatest diameter) and a porous double layer Ti + HA (ISO 5832-2 + ISO 13779-2) (fig. 09) or a porous composite layer of Ti with HA (all types of ELiS), (ISO 5832-2 + ISO 13779-2) (fig. 10) is applied to the entire surface. The outer spherical surface designed for the placement of the PE insert includes elements securing the insert and preventing it from falling out. The cup is constructed to allow for introduction via a K wire and has a central opening with the diameter of 2 mm in the bottom. The cup is made of moulded titanium alloy Ti6Al4V (ISO 5832-3).

Fig. 09 ELiS - Cementless cup T/II

Fig. 10 - ELiS - Sphere - Cup

- **The PE insert** has a spherical outer surface with a diameter matching the cup size (fig. 11). Securing features designed for connecting to the cup are in the upper part. The inner spherical surface of the insert is designed for articulation with the neck head with a diameter of 5 (mm). The PE insert is made of ultra-high molecular weight polyethylene (ISO 5834-2).

Fig. 11 - ELIS - PE insert

- **ELiS – Sphere or Konos, DM – Cup**

The cementless cup (Sphere, Konos) (fig. 12) DM consists of the cup (Sphere, Konos), where a DM neck with a PE insert is inserted. It is designed for affixing in the trapezium bone without using bone cement.

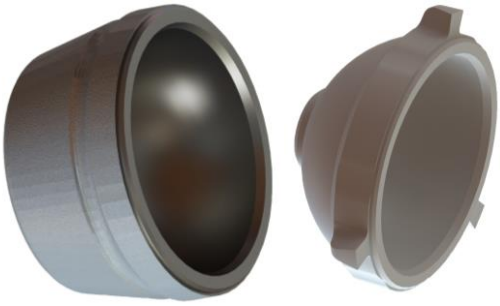

Fig. 12 - ELiS - Konos and Sphere

- **ELiS cup – Sphere, Konos – DM**

The cementless ELiS Sphere cup (fig. 13) has a spherical shape and Konos has a conical shape (fig. 14). Both cups come in the sizes of 9 or 10 mm. The inner articulation spherical surface is designed for inserting the PE neck insert, which is part of the neck (ELiS – DM) with the head with the diameter of 7.7 mm. The cup (ELiS – DM) does not have an opening for introduction via a K wire. The cup is made of wrought cobalt-chromium-molybdenum alloy (ISO 5832-12).

- The outer surface includes an osteointegration porous composite layer of Ti with HA (ISO 5832-2 + ISO 13779-2).

Fig. 13 - ELiS - Sphere, DM - Cup

Fig. 14 - ELiS - Sphere, DM - Cup

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- **ELiS – Cemented cup – type T/II and ELiS – Sphere – Cemented cup**

The cups are designed as cemented (ELiS – Cemented cup – type T/II – fig. 15) (ELIS – Sphere – Cemented cup – fig. 16). They are intended for configuration (II). The outer cup surface is a half-sphere with a diameter of 10 mm. The inner articulation surface is spherical and has a diameter of 5 mm. The stabilisation grooves along the circumference of the cup are intended for connecting with cement. They are made of ultra-high molecular weight polyethylene (ISO 5834-2). The cup (ELiS) also has a diagnostic element on its outer surface for easy identification of its position with X-ray. The diagnostic wire is made of stainless steel (ISO 5832-1).

Fig. 15 - ELiS - Cemented cup T/II

Fig. 16 - ELIS - SPHERE - Cemented cup

- **ELiS – Trapezium replacement – type TR**

The trapezium replacement set consists of two separate parts (a body of trapezium replacement and a PE insert – fig. 17) and is intended for complete replacement of the trapezium bone in the set for total replacement of the trapeziometacarpal joint.

Fig. 17 - Trapezium replacement

- The cementless **trapezium replacement body** is barrel shaped and has an elliptical cross-section (fig. 18). It is supplied in three sizes 14/15, 15/16 and 16/17 mm with the height of 10 mm. The outer surface includes a groove on one side for stabilisation using the radial part of the carpi radialis flexor and two transverse openings for additional auxiliary affixing. The inner part of the body is made with a conical opening for placement of the PE insert.

Fig. 18 - Trapezium replacement body

- The **PE insert** has a conical outer surface with dimensions matching the size of the opening in the replacement body (fig. 19). The inner spherical surface is designed for articulation with the neck head with a diameter of 5 mm. The replacement body is made of wrought cobalt-chromium-molybdenum alloy (ISO 5832-12). The outer surface is polished. The PE insert is made of ultra-high molecular weight polyethylene (ISO 5834-2).

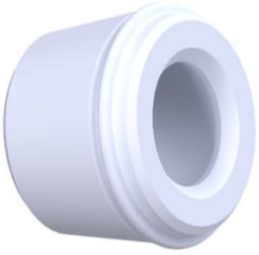


Fig. 19 - Trapezium insert

The MD referred to in section 3.1:

- Is intended for single use;
- Is supplied sterile by the manufacturer;
- Sterilisation method – ethylene oxide (EO).

Materials that may cause an allergic reaction:

- Ti, Al, V, Co, Cr, Mo, UHMWPE, HAp, bone cement.

3.2 Previous generations or variants

- First generation:

The clinical trial with TEP TMCJ commenced in 2011 in Havlíčkův Brod, where total replacement of the trapeziometacarpal joint was implanted to 8 patients. The total replacement contains the basic size series of stems, which come in sizes from 1 to 5, and coating with titanium plasma spray. The necks are in two basic variants, which differ in the angle of the transitional part with the spherical head (0° and 15°). Each of these neck variants comes in two versions, one for the cementless cup and one for the cemented

cup. Each variant is supplied in 4 different lengths. The cups are supplied in two versions – cementless and cemented. This total replacement obtained the CE marking in 2012 and since then thousands of replacements have been implanted without a single adverse event being reported.

Fig. 20 - First generation

- **Second generation:**

Following the success of the first generation of the total replacement of the trapeziometacarpal joint, a new clinical trial entitled TEP TMCJ/II was commended in 2014 in Havlíčkův Brod, where 8 patients received the extended version of the replacement. Compared to the first generation, the stems newly included Ti+Hap coating applied with plasma spray. The necks come again in two variants (straight and valgus), which differ in the angle of the transitional part. Each of these variants come in two versions, one for the cementless cup and one for trapezium replacement. The cups consist of two parts (the cup and the PE insert) and are made in two cup diameters. The trapezium replacement – TR type consists of two separate parts (the body and the insert) and is intended for total trapezium replacement in the set for total replacement of the trapeziometacarpal joint.

The aim in this second generation was to extend the variability of trapeziometacarpal joint replacement configurations and include the option of replacing the entire trapezium bone. The CE marking was obtained in 2015. More than one thousand replacements have been sold since without a single complaint or adverse event being reported.

Fig. 21 - Second generation

- **Third generation:**

The clinical trial with the third generation of the total replacement of the trapeziometacarpal joint was conducted in 2020. The purpose of the last generation was to further extend the wide range available for replacement configuration. The stems were designed with a new composite spray coating (combination of Ti+HAp) and intermediate sizes were included to fill the gaps in the range of sizes. Necks are newly made in additional versions – ante and valgus, and in the dual mobility version. This also applies to cups, which are made in the Konos and Sphere version. The aim of dual mobility is to ensure greater movement range of the replacement as a whole. Replacements with dual mobility are currently the most sought-after version on the market.

The third generation further extends the options for total replacement configuration according to the surgeons' preferences. The replacement offers a wide range of options for configurating the replacement optimally for the relevant indication. The last generation obtained the CE marking in 2021. Dozens of replacements have been implanted to this day.

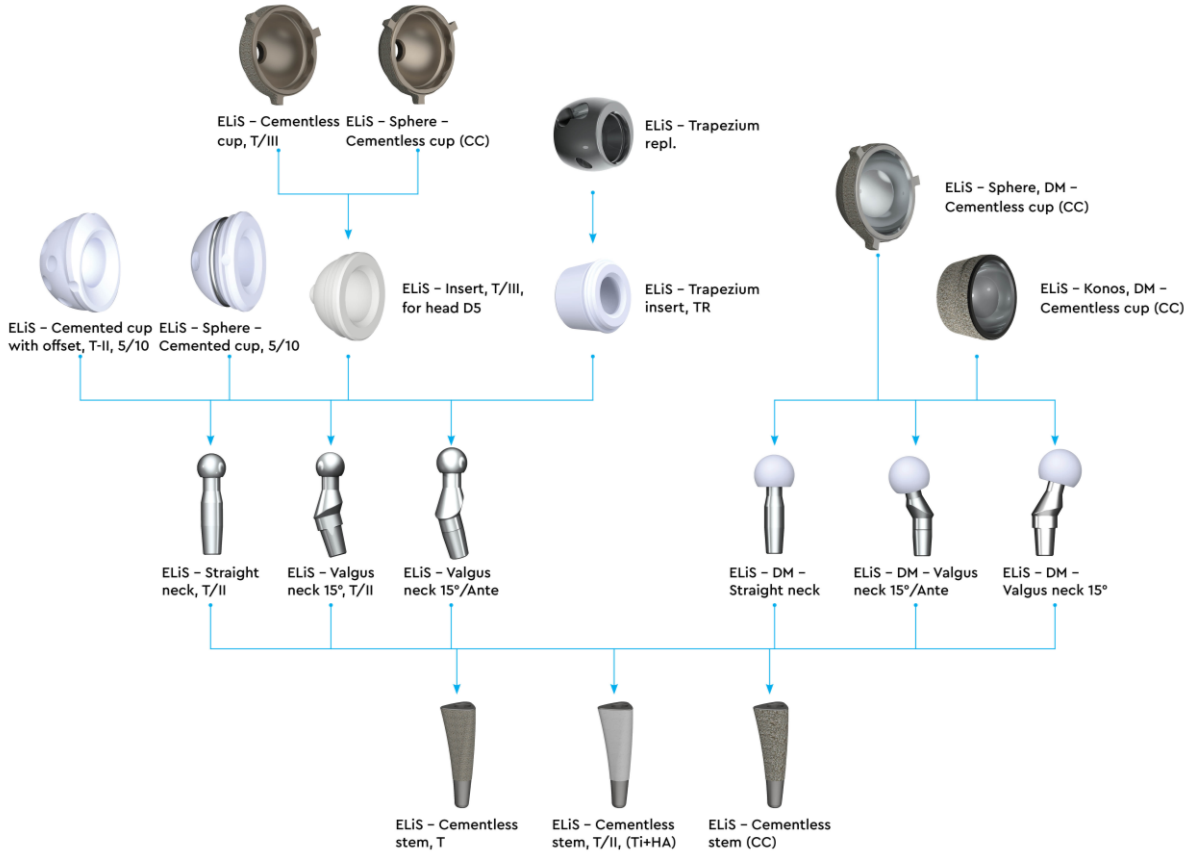
Fig. 22 - Third generation

3.3 List of accessories

- The medical device does not contain any accessories in the sense of the definition pursuant to the MDR.

3.4 List and description of various configurations and/or variants:

ELiS – Admissable combinations



4. Information on any residual risks and any undesirable effects, warnings and precautions

4.1 Residual risks and undesirable effects

- Residual risks: Risk of MD failure, if the user fails to observe the requirements for use listed in the instructions for use.

Potential adverse complications associated with surgery:

- During surgery
  - Damage to the venous and nervous structures
  - Iatrogenic bone damage, sometimes even fracture
- After surgery
  - Cardiovascular conditions, such as thromboembolic disease, deep phlebothrombosis, MI, postoperative haematoma
  - Wound healing disorders, infections
  - Loosening of the entire total replacement or its component, deformation or breakage of a component, flexion contracture, shortened limb

- Risks associated with repeated use from patient's point of view:
  - Failure of implants due to damage to the articulation, connecting and anchoring surfaces or unsuitable sterilisation – risk of early revision surgery
  - Risk of infection in patient – risk of infection with complicated healing and subsequent loosening
  - Accidental use of the wrong implant size or type or an incomplete implant – risk of revision surgery or early revision surgery

4.2 Warnings and precautions

Manufacturer's recommendations:

- The implant should not be repeatedly sterilised or used due to the risk of:
  - Damage to the polished articulation surfaces
  - Damage to the connecting elements and anchoring surfaces
  - Damage to or contamination of the porous layer

Warnings and precautions:

- Before surgery
  - **Patient**
    - The patient consents to the surgery and the associated risks – see the section on adverse complications;
    - The patient needs to be mentally capable of understanding the significance of the surgery and observe the postoperative regimen;
    - The patient needs to be aware of the limitations presented by the implant.
  - **Workplace performing the surgery**
    - Physician's qualification – orthopaedist, surgeon, traumatologist;
    - Ensuring highly sterile operative conditions;
    - Checks sterility of the packaging (damage to the packaging and expiry date);
    - Instruments used for the implantation procedure must be complete and functional;
    - Need to use exclusively the instruments supplied by the manufacturer and refrain from using any other instruments;
    - The implant is intended for single use only;
    - Ensuring that a damages, non-sterile or reused implant is not used;
    - Contacting the manufacturer at the address provided at the end of the instructions for use in the case of damage to the transport or outer packaging;
    - Disposing of the product in the case of damage to the outer packaging – see the section Disposing of the product;
    - Not using the implant in patients with documented allergies to or intolerance of metals (Ti, Al, V, Co, Cr, Mo, UHMWPE, HAp, bone cement);

- Patients receiving the trapeziometacarpal joint replacement must be informed that the lifespan of the implant depends on their weight and the level of their activity;
- All necessary implantation components must be available.

- **During surgery**
  - The instruments supplied by the manufacturer must be used during the application and the surgical procedure recommended by the manufacturer must be observed;
  - Surgical gloves must be used when handling the product;
  - It is necessary to avoid incorrect resection or incorrect positioning of the components;
  - The polished articulation surfaces, the surfaces coated with Ti or Ti + HA plasma spray, and the thread surfaces of the stem need to be protected while handling the product. Damages surface of the articulation surfaces has a negative effect on the lifespan of the implant;
  - Damaged instruments or equipment must not be used when introducing the implant;
  - Necks may not be used for test jointing;
  - When using the configuration with the cemented cup, all loose bone cement needs to be removed; pieces of bone cement may be left between the friction surfaces and thus cause abnormal wear and tear of the implant;
  - Always introduce the implant in a precisely prepared (verified with test components), clean and dry bed;
  - The articulation surfaces must be perfectly clean during test and final jointing;
  - Clean and dry the anchoring and articulation surfaces thoroughly before inserting the final neck.
- After surgery
  - Patient
    - The patient needs to be aware of the limitations presented by the implant (observe the strict postoperative regimen during the first three months – limit stress on the limb and avoid any vibration);
    - The patient needs to be warned that their new implant may only be put under limited stress until the bones have healed entirely;
    - We recommend consultation with a specialist in the case of any unexpected changes (any changes to the medical condition (also in the case of pregnancy for women)) that may concern the implant;
    - Based on the available information, patients with implants by BEZNOSKA, s.r.o. may undergo magnetic resonance imaging with a static magnetic field up to 3T, but no sooner than 6 weeks after the implantation and if no signs of loosening are present (see the Declaration of Admissibility of Magnetic Resonance Imaging + methodical sheet for examining patient with metal implants with MR + contraindications and risks of examination using MR –

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the information is available at https://www.beznoska.cz/pro-pacienty/nejcastejsi-otazky)

- Workplace performing the surgery
  - The load bearing capacity of the implant is not comparable with a healthy bone;
  - Performing timely preventative checks of the artificial joint.

4.3 Other relevant aspects of safety

- The MD has not been subject to corrective safety measure in the field.

5. The summary of clinical evaluation and relevant information on post-market clinical follow-up

5.1 Summary of clinical data related to equivalent device

- Not applicable.

  The MD is not compared against an equivalent device during a clinical trial, as clinical trials of the MD are conducted.

5.2 Summary of clinical data from conducted investigations of the device before CE-marking

5.2.1 Clinical trial of KZ TEP TMCJ – type T – 2010/5

5.2.1.1 Identification

The trial was conducted pursuant to Act No.123/2000 Coll., on medical devices, as amended, and Decree No. 316/2000 Coll., stipulating the requirements applicable to final reports on clinical trials of MDs. Statement of SÚKL on the approval of the CT dated 28/02/2011 Sukls226417/2010.

- Title: **Clinical trial of total replacement of the trapeziometacarpal joint**
- Reference: "**TEP TMCJ – type T – 2010/5**"
- Identification number: **2010/5**

5.2.1.2 Identification of the device, including any model numbers/versions

- Investigational product:

Cementless stem for TEP TMCJ – type T/I (ordering number):

Stem TEP TMCJ cementless – type T/I, size 1	413001
Stem TEP TMCJ cementless – type T/I, size 2	413002
Stem TEP TMCJ cementless – type T/I, size 3	413003
Stem TEP TMCJ cementless – type T/I, size 4	413004
Stem TEP TMCJ cementless – type T/I, size 5	413005

Neck for TEP TMCJ – type T/Ia (ordering number):

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Neck TEP TMCJ – type T/Ia – straight, 10 mm (d 7 mm)	413011
Neck TEP TMCJ – type T/Ia – straight, 12 mm (d 7 mm)	413012
Neck TEP TMCJ – type T/Ia – straight, 14 mm (d 7 mm)	413013
Neck TEP TMCJ – type T/Ia – straight, 16 mm (d 7 mm)	413014
Neck TEP TMCJ – type T/Ia – straight, 18 mm (d 7 mm)	413015
Neck TEP TMCJ – type T/Ia – valg.15°, 10 mm (d 7 mm)	413021
Neck TEP TMCJ – type T/Ia – valg.15°, 12 mm (d 7 mm)	413022
Neck TEP TMCJ – type T/Ia – valg.15°, 14 mm (d 7 mm)	413023
Neck TEP TMCJ – type T/Ia – valg.15°, 16 mm (d 7 mm)	413024
Neck TEP TMCJ – type T/Ia – valg.15°, 18 mm (d 7 mm)	413025
Neck TEP TMCJ – type T/Ia – ante.10°, 10 mm (d 7 mm)	413031
Neck TEP TMCJ – type T/Ia – ante.10°, 12 mm (d 7 mm)	413032
Neck TEP TMCJ – type T/Ia – ante.10°, 14 mm (d 7 mm)	413033
Neck TEP TMCJ – type T/Ia – ante.10°, 16 mm (d 7 mm)	413034
Neck TEP TMCJ – type T/Ia – ante.10°, 18 mm (d 7 mm)	413035
Neck TEP TMCJ – type T/Ia – valg.15°, ante.10°(L), 10 mm (d 7 mm)	413041
Neck TEP TMCJ – type T/Ia – valg.15°, ante.10°(L), 12 mm (d 7 mm)	413042
Neck TEP TMCJ – type T/Ia – valg.15°, ante.10°(L), 14 mm (d 7 mm)	413043
Neck TEP TMCJ – type T/Ia – valg.15°, ante.10°(L), 16 mm (d 7 mm)	413044
Neck TEP TMCJ – type T/Ia – valg.15°, ante.10°(L), 18 mm (d 7 mm)	413045
Neck TEP TMCJ – type T/Ia – valg.15°, ante.10°(R), 10 mm (d 7 mm)	413051
Neck TEP TMCJ – type T/Ia – valg.15°, ante.10°(R), 12 mm (d 7 mm)	413052
Neck TEP TMCJ – type T/Ia – valg.15°, ante.10°(R), 14 mm (d 7 mm)	413053
Neck TEP TMCJ – type T/Ia – valg.15°, ante.10°(R), 16 mm (d 7 mm)	413054
Neck TEP TMCJ – type T/Ia – valg.15°, ante.10°(R), 18 mm (d 7 mm)	413055

Cementless cup for TEP TMCJ – type T/Ia (ordering number):

Cup TEP TMCJ cementless – type T/Ia – 9 mm	413061
Cup TEP TMCJ cementless – type T/Ia – 10 mm	413062

Neck for TEP TMCJ – type T/Ib (ordering number):

Neck TEP TMCJ – type T/Ib – straight, 10 mm (d 7 mm)	413111
Neck TEP TMCJ – type T/Ib – straight, 12 mm (d 7 mm)	413112

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Neck TEP TMCJ – type T/Ib – straight, 14 mm (d 7 mm)	413113
Neck TEP TMCJ – type T/Ib – straight, 16 mm (d 7 mm)	413114
Neck TEP TMCJ – type T/Ib – straight, 18 mm (d 7 mm)	413115
Neck TEP TMCJ – type T/Ib – valg.15°, 10 mm (d 7 mm)	413121
Neck TEP TMCJ – type T/Ib – valg.15°, 12 mm (d 7 mm)	413122
Neck TEP TMCJ – type T/Ib – valg.15°, 14 mm (d 7 mm)	413123
Neck TEP TMCJ – type T/Ib – valg.15°, 16 mm (d 7 mm)	413124
Neck TEP TMCJ – type T/Ib – valg.15°, 18 mm (d 7 mm)	413125
Neck TEP TMCJ – type T/Ib – ante.10°, 10 mm (d 7 mm)	413131
Neck TEP TMCJ – type T/Ib – ante.10°, 12 mm (d 7 mm)	413132
Neck TEP TMCJ – type T/Ib – ante.10°, 14 mm (d 7 mm)	413133
Neck TEP TMCJ – type T/Ib – ante.10°, 16 mm (d 7 mm)	413134
Neck TEP TMCJ – type T/Ib – ante.10°, 18 mm (d 7 mm)	413135
Neck TEP TMCJ – type T/Ib – valg.15°, ante.10°(L), 10 mm (d 7 mm)	413141
Neck TEP TMCJ – type T/Ib – valg.15°, ante.10°(L), 12 mm (d 7 mm)	413142
Neck TEP TMCJ – type T/Ib – valg.15°, ante.10°(L), 14 mm (d 7 mm)	413143
Neck TEP TMCJ – type T/Ib – valg.15°, ante.10°(L), 16 mm (d 7 mm)	413144
Neck TEP TMCJ – type T/Ib – valg.15°, ante.10°(L), 18 mm (d 7 mm)	413145
Neck TEP TMCJ – type T/Ib – valg.15°, ante.10°(R), 10 mm (d 7 mm)	413151
Neck TEP TMCJ – type T/Ib – valg.15°, ante.10°(R), 12 mm (d 7 mm)	413152
Neck TEP TMCJ – type T/Ib – valg.15°, ante.10°(R), 14 mm (d 7 mm)	413153
Neck TEP TMCJ – type T/Ib – valg.15°, ante.10°(R), 16 mm (d 7 mm)	413154
Neck TEP TMCJ – type T/Ib – valg.15°, ante.10°(R), 18 mm (d 7 mm)	413155

Cementless cup for TEP TMCJ – type T/Ib (ordering number):

Cup TEP TMCJ cementless – type T/Ib – 9 mm	413161
Cup TEP TMCJ cementless – type T/Ib – 10 mm	413162

Neck for TEP TMCJ – type T/II (ordering number):

Neck TEP TMCJ – type T/II – straight, 10 mm (d 5 mm)	413071
Neck TEP TMCJ – type T/II – straight, 12 mm (d 5 mm)	413072
Neck TEP TMCJ – type T/II – straight, 14 mm (d 5 mm)	413073
Neck TEP TMCJ – type T/II – straight, 16 mm (d 5 mm)	413074

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Neck TEP TMCJ – type T/II – straight, 18 mm (d 5 mm)	413075
Neck TEP TMCJ – type T/II – valg.15°, 10 mm (d 5 mm)	413076
Neck TEP TMCJ – type T/II – valg.15°, 12 mm (d 5 mm)	413077
Neck TEP TMCJ – type T/II – valg.15°, 14 mm (d 5 mm)	413078
Neck TEP TMCJ – type T/II – valg.15°, 16 mm (d 5 mm)	413079
Neck TEP TMCJ – type T/II – valg.15°, 18 mm (d 5 mm)	413080

Cemented cup for TEP TMCJ– type T/II (ordering number):

Cup TEP TMCJ cemented – type T/II – standard 9 mm	413081
Cup TEP TMCJ cemented – type T/II – offset 9 mm	413082

5.2.1.3 Intended purpose of the investigational device

- Total replacement of the trapeziometacarpal joint

5.2.1.4 Study objectives

- Flawlessness of the instruments;
- Functional parameters of the implant;
- Impact on the proposed implant design on the long-term functioning of the TMC joint, especially in view of monitoring of pain and durability.

5.2.1.5 Study concept

- Randomized, controlled trial

5.2.1.6 Primary and secondary observed parameters

- Subjective assessment according to DASH and VAS
- Objective assessment:
  a/ Jamar grip strength of the thumb
    - Key pinch test
    - Tip pinch test
    - Hand grip test (grasp)

  b/ Range of thumb movement (according to Kapandji)
    - Opposition (thumb against fingers and little finger)
    - Counter-opposition (retropulsion)
- Assessment of overall patient satisfaction, responses to questions
  - Are you satisfied with the outcomes of the surgery (highly satisfied, satisfied, dissatisfied, deeply dissatisfied)
  - If surgery was needed on the other hand and endoprosthesis was recommended to you, would you agree? (yes/no)

5.2.1.7 Inclusion/exclusion criteria for selection of subjects

- Inclusion criteria
  - Trial subjects must have the following indications: primary and secondary rhizarthrosis resistant to conservative treatment, rheumatoid arthritis is also a

relative indication, Eaton-Littler II-III X-ray criterion (Comtet I-II), unfixed Z deformity of the thumb in the MCP joint (Teissier), rather „in"active type, trapezium height > 7 mm.

- Exclusion criteria
  - For example, cases where undesirable removal of the implant needs to be performed due to complicated healing (such as an infection), instability of the implant due to incorrect indication, internal complications, patient's death and any other reasons considered by the treating physician can be deemed early termination of the trial subject's participation.

5.2.1.8 Number of enrolled subjects

- 8 trial subjects

5.2.1.9 Study target group

- Adult population with completed growth, men, women
- Nationality - irrelevant

5.2.1.10 Summary of study methods

- DASH and VAS
- Jamar
- Kapandji

See section 5.2.1.6.

5.2.1.11 Summary of results

- Clinical benefits
  - Significant improvement of the function and the range of movement, the joint has sufficient stability.

    All objectives specified in the CT plan (assessment of the operative instruments, functional parameters of the MD and clinical outcomes) were achieved.
- Adverse side effects
  - There are no known adverse side effects, the MD does not contain any pharmaceutical products.
- Follow-up
  - Five years after the implantation:
    - VAS reached the value of 0.2 (the average value from preoperative assessments was 8.2), which means significant improvement (a joint free of pain has the VAS value of 0). The objective was achieved.
    - DASH reached the value of 5.0 (the average value from preoperative assessments was 56.7), which means significant improvement of the ability to perform the relevant tasks according to DASH). The objective was achieved.

  - There was a significant increase in the grip strength according to Jamar HGS 311, KP 74, TP 73 (the values from preoperative assessment were HGS 151, KP 21.6, TP 19.6). The objective was achieved.
  - The following outcomes were achieved in subjective assessment (1. with the outcome of the surgery, 2. benefit, 3. agree to another surgery based on the experience with the outcome): 1. – highly satisfied, 2. – 7x significantly higher level of satisfaction, 1x higher level of satisfaction, 3. – definitely. The objective was achieved.
- Percentage of follow-up completion
  - 100%
- Is the study ongoing?
  - No

    The CT was completed on 03/04/2012 with the Final Report, the follow-up was completed on 06/10/2016 With the Report on Clinical Follow-up of Patients after Completion of the CT – assessment after 60 months following the implantation.
- Any study limitations
  - N/A
- Any shortcomings of the device and any replacements of the device associated with safety and/or effectiveness during the study
  - N/A

5.2.2 Clinical trial of KZ TEP TMCJ/II – type T – 2014/1

5.2.2.1 Identification

The trial was conducted pursuant to Act No.123/2000 Coll., on medical devices, as amended, and Decree No. 316/2000 Coll., stipulating the requirements applicable to final reports on clinical trials of MDs. Statement of SÚKL on the approval of the CT dated 09/10/2014 Sukls116618/2014.

- Title: TEP TMCJ/II – 2014/1"
- Identification number: 2014/1

5.2.2.2 Identification of the device, including any model numbers/versions

- Investigational product:

Cementless stem for TEP TMCJ – type T/I (ordering number):

Stem TEP TMCJ cementless – type T/II, size 1	413011
Stem TEP TMCJ cementless – type T/II, size 2	413012
Stem TEP TMCJ cementless – type T/II, size 3	413013
Stem TEP TMCJ cementless – type T/II, size 4	413014
Stem TEP TMCJ cementless – type T/II, size 5	413015

Cementless cup for TEP TMCJ – type T/III (ordering number):

Cementless cup TEP TMCJ– type T/III– 9 mm	413171

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Cementless cup TEP TMCJ– type T/III– 10 mm	413172
PE insert cementless cup TEP TMCJ – type T/III – for head 5 mm	413175

Trapezium replacement for TEP TMCJ – type TR (ordering number):

Náhrada trapézia pro TEP TMCJ– typ TR – vel. 14/15 - 9	413180
Náhrada trapézia pro TEP TMCJ– typ TR – vel. 15/16 - 10	413181
Náhrada trapézia pro TEP TMCJ– typ TR – vel. 16/17 - 11	413182

Trapezium replacement PE insert for TEP TMCJ – type TR (ordering number):

Trapezium replacement PE insert TEP TMCJ– type TR – size 9/5	413191
Trapezium replacement PE insert TEP TMCJ– type TR – size 10/5	413192
Trapezium replacement PE insert TEP TMCJ– type TR – size 11/5	413195

5.2.2.3 Intended purpose of the investigational device

- Total replacement of the trapeziometacarpal joint

5.2.2.4 Study objectives

- Flawlessness of the instruments – secondary objective;
- Functional parameters of the implant – primary objective;
- Impact on the proposed implant design on the long-term functioning of the TMC joint, especially in view of monitoring of pain and durability.

5.2.2.5 Study concept

- Randomized, controlled trial

5.2.2.6 Primary and secondary observed parameters

- Subjective assessment according to DASH and VAS
- Objective assessment:
  a/ Jamar grip strength of the thumb
    - Key pinch test
    - Tip pinch test
    - Hand grip test (grasp)

  b/ Range of thumb movement (according to Kapandji)
    - Opposition (the thumb against the little finger)
    - Radial abduction
    - Palmar abduction
- Assessment of overall patient satisfaction, responses to questions
  - Are you satisfied with the outcomes of the surgery (highly satisfied, satisfied, dissatisfied, deeply dissatisfied)
  - If surgery was needed on the other hand and endoprosthesis was recommended to you, would you agree? (yes/no)

5.2.2.7 Inclusion/exclusion criteria for selection of subjects

- Inclusion criteria

  - Trial subjects must have the following indications: primary and secondary rhizarthrosis resistant to conservative treatment, rheumatoid arthritis is also a relative indication, Eaton-Littler II-IV X-ray criterion, unfixed Z deformity of the thumb in the MCP joint, trapezium height (not applicable to trapezium replacement) > 7 mm. Subjects were informed by the investigator about the benefits and risks associated with their participation in the CT, they need to be aware of the benefits and risks associated with the CT and sign the informed consent;
- Exclusion criteria
  - For example, cases where undesirable removal of the implant needs to be performed due to complicated healing (such as an infection), instability of the implant due to incorrect indication, internal complications, patient's death and any other reasons considered by the treating physician can be deemed early termination of a trial subject's participation.

5.2.2.8 Number of enrolled subjects

- 8 trial subjects

5.2.2.9 Study target group

- Adult population with completed growth, men, women
- Nationality - irrelevant

5.2.2.10 Summary of study methods

- DASH and VAS
- Jamar
- Kapandji

See section 5.2.2.6.

5.2.2.11 Summary of results

- Clinical benefits
  - Significant improvement of the function and the range of movement, the joint has sufficient stability

    All objectives specified in the CT plan (assessment of the operative instruments, functional parameters of the MD and clinical outcomes) were achieved.
- Adverse side effects
  - There are no known adverse side effects, the MD does not contain any pharmaceutical products.
- Follow-up
  - Five years (or 7.5 years) after the implantation:
    - VAS reached the value of 0.6 (the average value from preoperative assessments was 5.68), which means significant improvement (a joint free of pain has the VAS value of 0). The average reduction by 91.5% was reported. The objective was achieved.

- QuickDASH reached the value of 6.82 (the average value from preoperative assessments was 66.54), which means significant improvement of the ability to perform the relevant tasks according to QuickDASH). The average reduction by 67.7 % was reported. The objective was achieved.
- There was a significant increase in the key pinch strength according to Jamar KP 71.14, hand grip strength HGS 266 (the values from preoperative assessment were KP 31.86 HGS 190.14). KP improved by 227 %, HGS o 97,6 %. The objective was achieved.
- The subjective assessment of satisfaction with the surgery was rated at 1.33, and the rating did not change throughout the follow-up. Satisfaction ranged between highly satisfied and a significantly higher level of satisfaction. The objective was achieved.

- Percentage of follow-up completion

  Of the 8 trial subjects, one subject was excluded from the follow-up period (5 – 7.5 years after the implantation) due to cancer diagnosis, which prevented the subject from undergoing clinical and X-ray assessments; the subject remains in the case of the oncological department. This subject's results from the last examination (after 3 years) were excellent (opposition – 9 out of 10 points, preoperative result of 3 points; key pinch strength KP = 60 N, HGS = 195 N, preoperative results KP = 15 N, HGS = 81 N; VAS score of joint pain – (max. value of 10, min. 0), 0 – no pain, preoperative result 9.5; QuickDASH work and sport/musical performance module score 2.27, preoperative result of 81.8 points, which means improvement by 97 %.

  The percentage of follow-up completion after three years was 100 %, subsequently dropping to 87.5 % after the exclusion of one patient for assessment 5 or 7.5 years after the implantation of the MD.

- Is the study ongoing?
  - No

    The CT was completed on 28/04/2015 with the Final Report, the follow-up was completed on 03/05/2022 with the Report on Clinical Follow-up of Patients after Completion of the CT – assessment 5 or 7.5 years after the implantation.

- Any study limitations
  - N/A
- Any shortcomings of the device and any replacements of the device associated with safety and/or effectiveness during the study
  - N/A

5.2.3 Clinical trial of TEP TMCJ/III– 2019/1

5.2.3.1 Identification

The trial was conducted pursuant to Act No.268/2014 Sb., on medical devices and on changes to Act No. 634/20004 Coll., on administrative fees, as amended. Statement of

SÚKL on the approval of the CT dated 06/05/2020 Sukls104344/2019, ref. no. sukl113169/2020

- Title: TEP TMCJ/III
- CT identification number: 2019/1
- CIP identification number: 2019/1-2
- CIP version: 4

5.2.3.2 Identification of the device, including any model numbers/versions

- Investigational MD:

Investigational medical devices – implants	
Ordering number	**Trade name**
413021	ELiS - Cementless stem, (CC), 1
413026	ELiS - Cementless stem, (CC), 1+
413022	ELiS - Cementless stem, (CC), 2
413027	ELiS - Cementless stem, (CC), 2+
413023	ELiS - Cementless stem, (CC), 3
413024	ELiS - Cementless stem, (CC), 4
413025	ELiS - Cementless stem, (CC), 5
413028	ELiS - Cementless stem, (CC), 5+
413173	ELiS - Sphere - Cementless cup (CC), D9
413174	ELiS - Sphere - Cementless cup (CC), D10
413092	ELiS - Sphere - Cemented cup, 5/10
413087	ELiS - Valgus neck 15°/Ante-R, 5/12
413088	ELiS - Valgus neck 15°/Ante-R, 5/14
413089	ELiS - Valgus neck 15°/Ante-R, 5/16
413090	ELiS - Valgus neck 15°/Ante-R, 5/18
413097	ELiS - Valgus neck 15°/Ante-L, 5/12
413098	ELiS - Valgus neck 15°/Ante-L, 5/14
413099	ELiS - Valgus neck 15°/Ante-L, 5/16
413100	ELiS - Valgus neck 15°/Ante-L, 5/18
413176	ELiS - Sphere, DM - Cementless cup (CC), D9
413177	ELiS - Sphere, DM - Cementless cup (CC), D10
413178	ELiS - Konos, DM - Cementless cup (CC), D9
413179	ELiS - Konos, DM - Cementless cup (CC), D10
413062	ELiS - DM - Straight neck, 7.7/12
413063	ELiS - DM - Straight neck, 7.7/14
413064	ELiS - DM - Straight neck, 7.7/16
413065	ELiS - DM - Straight neck, 7.7/18
413067	ELiS - DM - Valgus neck 15°, 7.7/12
413068	ELiS - DM - Valgus neck 15°, 7.7/14
413069	ELiS - DM - Valgus neck 15°, 7.7/16

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413070	ELiS - DM - Valgus neck 15°, 7.7/18
413054	ELiS - DM - Valgus neck 15°/Ante-L, 7.7/12
413055	ELiS - DM - Valgus neck 15°/Ante-L, 7.7/14
413056	ELiS - DM - Valgus neck 15°/Ante-L, 7.7/16
413057	ELiS - DM - Valgus neck 15°/Ante-L, 7.7/18
413058	ELiS - DM - Valgus neck 15°/Ante-R, 7.7/12
413059	ELiS - DM - Valgus neck 15°/Ante-R, 7.7/14
413060	ELiS - DM - Valgus neck 15°/Ante-R, 7.7/16
413061	ELiS - DM - Valgus neck 15°/Ante-R, 7.7/18

Investigational medical devices – instruments	
Ordering number	**Trade name**
400455	ELiS - Rasp, 1+
400456	ELiS - Rasp, 2+
400457	ELiS - Rasp, 5+
400306	ELiS - Trial stem, 1+
400307	ELiS - Trial stem, 2+
400308	ELiS - Trial stem, 5+
400477	ELiS - Loader coupler
400478	ELiS - Stem loader/extractor II
400479	Open-end wrench, 7
400471	ELiS - Dipstick with drilling sleeve II, D9
400485	ELiS - Aiming device
400436	Guide wire, D1.2, L50
400464	Guide wire, D1.8, L50
400465	Guide wire, D1.8, L110
400407	ELiS - "T" head, for reamers
400484	ELiS - Alignment reamer III
400480	ELiS - Cannulated countersink II
400481	ELiS - Reamer II, D8
400482	ELiS - Reamer II, D9
400483	ELiS - Reamer II, D10
400493	Konos - Pre-drill bit
400497	Konos - Cone reamer, D9
400498	Konos - Cone reamer, D10
400494	Konos - Guide wire impactor
400495	Konos - Finishing cone, D9
400496	Konos - Finishing cone, D10
400472	ELiS - Template II, D9
400473	ELiS - Template II, D10
400486	ELiS - Dual mobility template, D9

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400487	ELiS - Dual mobility template, D10
400489	Konos - Template, D9
400490	Konos - Template, D10
400475	ELiS - Curved loader II, 7
400476	ELiS - Direct loader II, 7
400391	ELiS - Trial neck, valgus 15°/ANTE-L, 5/12
400392	ELiS - Trial neck, valgus 15°/ANTE-L, 5/14
400393	ELiS - Trial neck, valgus 15°/ANTE-L, 5/16
400394	ELiS - Trial neck, valgus 15°/ANTE-L, 5/18
400381	ELiS - Trial neck, valgus 15°/ANTE-R, 5/12
400382	ELiS - Trial neck, valgus 15°/ANTE-R, 5/14
400383	ELiS - Trial neck, valgus 15°/ANTE-R, 5/16
400384	ELiS - Trial neck, valgus 15°/ANTE-R, 5/18
400281	ELiS - DM - Trial neck, straight, 7.7/12
400282	ELiS - DM - Trial neck, straight, 7.7/14
400283	ELiS - DM - Trial neck, straight, 7.7/16
400284	ELiS - DM - Trial neck, straight, 7.7/18
400291	ELiS - DM - Trial neck, valgus 15°, 7.7/12
400292	ELiS - DM - Trial neck, valgus 15°, 7.7/14
400293	ELiS - DM - Trial neck, valgus 15°, 7.7/16
400294	ELiS - DM - Trial neck, valgus 15°, 7.7/18
400277	ELiS - DM - Trial neck, valgus 15°/ANTE-L, 7.7/12
400278	ELiS - DM - Trial neck, valgus 15°/ANTE-L, 7.7/14
400279	ELiS - DM - Trial neck, valgus 15°/ANTE-L, 7.7/16
400280	ELiS - DM - Trial neck, valgus 15°/ANTE-L, 7.7/18
400273	ELiS - DM - Trial neck, valgus 15°/ANTE-R, 7.7/12
400274	ELiS - DM - Trial neck, valgus 15°/ANTE-R, 7.7/14
400275	ELiS - DM - Trial neck, valgus 15°/ANTE-R, 7.7/16
400276	ELiS - DM - Trial neck, valgus 15°/ANTE-R, 7.7/18
400424	ELiS - Holding pliers, dual mobility
400427	ELiS - Cup loader, dual mobility
400428	ELiS - Fixed neck extractor II
400429	ELiS - Adjustable neck extractor (D7.7), dual mobility

5.2.3.3 Intended purpose of the investigational device

- The main purpose of the IMD, i. e. TEP types ELiS Sphere, ELiS Sphere DM and ELiS Konos DM, is to improve the quality of life for patients suffering from pain in the trapeziometacarpal joint due to instability of the joint or due to significant damage to the articulation surfaces, which cannot be addressed with conservative treatment. The IMD performs the function of a healthy joint;
- Total replacement of the trapeziometacarpal joint.

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5.2.3.4 Study objectives

- The primary objective of the CT is to assess the performance parameters and safety of the IMD according to the increase in the range of motion in the TMCJ, improvement of grip performance and reduction on pain in this joint.
- The secondary objective of the CT is to verify the functionality of the application instruments and assess the surgical technique. This objective will be achieved by subjective assessment by the principal investigator.

5.2.3.5 Study concept

- Randomized, controlled trial

5.2.3.6 Primary and secondary observed parameters

- Subjective assessment according to QuickDASH and VAS
- Objective assessment:
  a/ Jamar grip strength of the thumb
    - Key Pinch test
    - Hand Grip Strength test
  b/ Range of thumb movement (according to Kapandji)
    - Opposition (the thumb against the little finger)
- Work and sport or musical performance module

5.2.3.7 Inclusion/exclusion criteria for selection of subjects

- Inclusion criteria
  - Trial subjects must have the following indications: primary, secondary and posttraumatic rhizarthrosis, rheumatoid arthritis. Subjects were informed by the investigator about the benefits and risks associated with their participation in the CT, they need to be aware of the benefits and risks associated with the CT and sign the informed consent;
- Exclusion criteria
  - Death or new implantation of the IMD are the criteria for discontinuing a subject's participation in the CT. New implantation may be caused by an infection, instability of the IMD, internal complications or other reasons to be assessed by the principal investigator in cooperation with the sponsor. In the case of withdrawal or discontinuation of a subject's participation, the relevant subject will not be included in the overall assessment of the CT and will not be followed up according to the follow-up schedule. Subjects who withdraw from the CT or whose participation in the CT is discontinued will continue to be assessed according to the decision of their treating physician.

5.2.3.8 *Number of enrolled subjects*

- 10 trial subjects

5.2.3.9 *Study target group*

- Adult population with completed growth, men, women
- Nationality - irrelevant

5.2.3.10 Summary of study methods

- QuickDASH and VAS
- Jamar
- Kapandji

See section 5.2.2.6.

5.2.3.11 Summary of results

- Clinical benefits
  - Improvement in the function of the TMCJ;
  - Reduction of pain in the TMCJ;
  - Improvement in the distribution of strength in the joint;
  - Improved healing with the IMD;
  - Reduced probability of luxation;
  - Variability of the IMD after addressing a greater range of operative situations;
  - Fast and precise surgical procedure.

  The objectives were achieved.

- Adverse side effects

  There are no known adverse side effects, the MD does not contain any pharmaceutical products.

- Follow-up
  - 12 months after the implantation:
    - VAS reached the value of 0.33 (the average value from preoperative assessments was 8.1), which means significant improvement (a joint free of pain has the VAS value of 0). There was the average reduction by 95.8 %. The objective was achieved.
    - QuickDASH reached the value of 3.28 (the average value from preoperative assessments was 71.76), which means significant improvement of the ability to perform the relevant tasks according to QuickDASH). There was the average reduction by 95.27 %. The objective was achieved.
    - There was significant improvement in the key pinch strength according to Jamar KP 65, hand grip strength HGS 286 (the values from preoperative assessment were KP 34 HGS 156). KP improved by 94.3 %, HGS by 78.1 %. The objective was achieved.
    - Range of movement **2.7x higher** than the minimum requirement
    - Key pinch strength (KP) is higher by **174.4 %** (minimum requirement: increase by 35 %)
    - Hand grip strength (HGS) is higher by **178.1 %** (minimum requirement: increase by 35 %)
    - Pain (VAS) is lower by **95.8 %** (minimum requirement: decrease by 45 %)
    - The outcome of the questionnaire on activities performed (QuickDASH) is lower by **95.16 %** (minimum requirement: decrease by 45 %)

  The objective was achieved.

- Percentage of follow-up completion
  - 12 months 100 %
- Is the study ongoing?
  - The CT was completed on 11/11/2022 with the Final Report, the follow-up after 12 months – on 07/12/2021 with the Report on Clinical Follow-up of Patients after Completion of the CT. No changes were reported as of 11/11/2022.
- Any study limitations
  - N/A
- Any shortcomings of the device and any replacements of the device associated with safety and/or effectiveness during the study
  - N/A

5.3 Summary of other clinical data and main findings

- **No** previously unknown adverse effects **have been identified**;
- **No** newly emerging risks **have been identified**;
- The continued acceptability of the benefit and risk ratio **has been confirmed**;
- **No** systematic and incorrect use of the MD or use outside the intended purpose **has been confirmed**;
- **There were no** quality complaints, complaints or adverse events, including adverse events in competition MDs;
- **No indication** of the need for preventative measures or corrective safety measures **was concluded** from the obtained information.

This was documented by the report on assessment of the post-market clinical follow-up (PMCF) Replacements for parts of the upper limb – replacement of the trapeziometacarpal joint dated 05/03/2022.

5.4 Overall summary of the clinical performance and safety

- The clinical performance, safety and effectiveness of the MD was confirmed by the achievement of the objectives listed in the activities:
  - C.1 Follow-up of the trial subject cohort from the clinical trial of the MD TEP TMCJ/II-2014/1 (after 5 or 7.5 years) and the MD TEP TMCJ/III-2019/1 (after 1 year) concluded in the Final Report dated 18/01/2021. *The objective was achieved.*
  - C.2 K-M curve of MD survival. *The objective was achieved.*
  - C.3 Cohort of patients for monitoring objective and subjective parameters (score). *The objective was achieved.*
  - C.4 Proactive and systematic process of gathering and using all available information.
    - No serious adverse event has occurred so far;
    - No safety corrective measures in the field have occurred so far;
    - Records concerning non-serious events and data on all adverse effects – no adverse effect has been reported over 10 years of use of the MD since its marketing;

- There has been no information on trend reports;
- Information obtained from relevantly specialised or technical literature, databases and/or registers.
- Conclusions/citations: Statistically significant improvement in the outcomes of the DAS and VAS score in using total replacement of the TMC joint has been confirmed. The application of the principle of dual mobility in trapeziometacarpal arthroplasty may improve the stability of these prostheses significantly. The radiolucent zones around the prosthesis elements are not systematic predictors of future loosening. No signs of loosening, tilting or dropping of the cup in any patient have been reported. We recommend implantation of this type of prosthesis due to beneficial clinical outcome and radiological performance. Compared to the resection interposition arthroplasty, the method using replacement of the TMJ with endoprosthesis is assessed more positively, despite the limited indication criteria. TM prostheses currently achieve better results than trapeziectomy over mid-term.

- C.5 Collection of data on post-market history. The objective was achieved. There were no deviations from the plan. More than 6,500 MDs have been sold since 2012.
- C.8 Effective and suitable methods and tools for investigating post-market complaints and analysing experiences gathered in the field. The methods and tools applied in this activity have not changed, and no indications of the need for this have been observed on the market. No complaint was reported during the monitored period.
- C.9 Methods and protocols for managing adverse events subject to trend reporting, including methods and protocols to be used to determine any statistically significant increase in the frequency or severity of adverse events, as well as the monitored period. Ne special adverse event subject to reporting trend in the reported anticipated side effects and their frequency has occurred during the monitoring period since marketing of the MD.
- C.10 Methods and protocols for effective communication with competent bodies, notified bodies, business entities and users. No adverse event reports, serious adverse event reports or suspicion of a serious adverse event have occurred since marketing of the MD.
- C.11 Procedures for compliance with the obligation of the MD manufacturer stipulated in Articles 83, 84 and 86 of the Regulation of the European Parliament and of the Council (EU) 2017/745. The procedures did not change during the monitored period of 2021. The objective was achieved in accordance with the PMCF plan.
- C.12 Systematic procedures for determining and initiating suitable measures, including corrective measures. The procedures did not change during the monitored period of 2021.

- C.13 Tools for detecting and determining devices requiring corrective measures. The tools for detecting and determining these MDs did not change during the monitored period of 2021.

This was documented in the Report on Assessment and Subsequent Post-market Clinical Follow-up (PMCF) for the replacement of a part of the upper limb – replacement of the trapeziometacarpal joint dated 03/05/2022, MD risk management MR12 – Replacement of a part of the upper limb dated 24/06/2022, Review Report for RM12 dated 24/06/2022.

5.5 Planned or ongoing PMCF

- The ongoing post-market clinical follow-up continues in two directions:

  Firstly, there is the follow-up of the cohort of patients from the clinical trial of the MD TEP TMCJ/III-2019/1 (after the 2nd year, the overall follow-up is to continue for 5 years after the implantation) concluded with the Final Report dated 18/01/2021.

  Secondly, there is the follow-up of the cohort of patients for assessment of the Kaplan-Meier curve of the MD survival.

- Planned clinical follow-up:

  Follow-up of the extended cohort of patients for assessment of the Kaplan-Meier curve of the MD survival.

No complications, new risks or unexpected failures of the MD have been detected in the clinical follow-up to date.

5.6 Information on clinical trial and PMCF intended for patients

5.6.1 Clinical context of the device

The medical devices have been marketed since 2012, and the third generation of the trapeziometacarpal joint is currently on the market. No adverse events, complaints or quality complaints have been reported throughout the period of sale. Several thousand products have been sold in the Czech Republic and abroad.

5.6.2 Clinical evidence for CE certification

Each generation of the trapeziometacarpal joint underwent CE certification. The first generation of the trapeziometacarpal joint was tested in the clinical trial in 2011. The functional parameters of the implant were verified in full, and the achievement of these parameters was confirmed during the follow-up. The implant design significantly improved the functioning of the trapeziometacarpal joint, reducing the VAS, DASH value. The second generation underwent clinical testing in 2014. The functional parameters of the implant were verified in full, and the achievement of these parameters was confirmed during the follow-up. The implant design significantly improved the functioning of the trapeziometacarpal joint, reducing the VAS, DASH value. The third generation underwent clinical testing in 2020. The functional parameters of the implant were verified in full, and the achievement of these parameters was confirmed during the follow-up. The implant design significantly

improved the functioning of the trapeziometacarpal joint, reducing the VAS, DASH value, the key pinch and hand grip strength improved.

5.6.3 Safety

5.6.3.1 Risk and benefit assessment

Prior to implantation of the MD, patients are negatively affected mostly by the poor grip strength in the thumb, reduced mobility, pain in the locomotor system, and the use of analgesics, which is eliminated in most cases after implantation of the MD.

The implantation of the MD, which is part of the surgery to perform total replacement of the trapeziometacarpal joint, brings positive impact on the clinical outcome and significant improvement in the patient's quality of life compared to the preoperative condition in the parameters listed below.

Overall summary

According to literature research, replacement of the trapeziometacarpal joint currently achieves better results in the treatment of rhizarthrosis and the associated risks are relatively mild. This is also supported by the results of the completed post-market follow-up, during which no complaint, quality complaint or adverse event occurred. Nonetheless, potential risks associated with implantation and long-term use of the replacement cannot be ruled out. Based on the available data, the benefit of the trapeziometacarpal joint (significant improvement in the mobility of the thumb joint, reduced pain) significantly outweighs the potential residual risk of the possible failure of the implant, even in the case of a different method of treating rhizarthrosis.

5.6.3.2 Gathering information

The PMCF specifies the methods and procedures stipulated by the manufacturer for active gathering and assessment of clinical data arising from internal and external use of the device. The information gathered in this manner is assessed regularly on an annual basis to confirm long-term safety and clinical effectiveness, and any improvement measures are taken as needed.

6. Possible diagnostic or therapeutic alternatives

- Conservative treatment (local transdermal treatment with drugs or patches)
  Treatment of joints with medication includes the use of products reducing pain and mitigating inflammation. This type of treatment is not entirely safe in many cases and causes problems in other organs, mainly in the digestive tract, liver, kidneys and heart. Local therapy and physiotherapy only provide temporary relief and sometimes no relief can be achieved with these means.
- Surgical – endoprosthesis with a competition MD, arthrodesis, interposition arthroplasty (trapeziectomy with plastic surgery using a tendon)
  - References to latest development (according to MDCG 2019-9)
    - Acta Chirurgiae Orthopaedicae et traumatologieae Čechosl., 1/2016; 27-31, J. Jurča, M. Němejc, V. Havlas – Comparison of the outcomes or surgical

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treatment of rhizarthrosis with interposition arthroplasty according to Burton-Pellegrini and implantation of a trapeziometacarpal endoprosthesis

- Medicína a umění 2/2018, str. 33-37: Trtík – Implants and trapeziometacarpal prostheses
- EFORT Open Rev 2021; 6:316-330, Thumb CMCJ prosthetic total joint replacement: a systematic review; Thomas J. Holme, Marta Karbowiak, Jennifer Clements, Ritesh Sharma, Johnathan Craik
- JHS(E) 2021, Dual mobility trapeziometacarpal prosthesis: a prospective study of 107 cases with a follow-up more than 3 years, Bruno Lussiez, Cyril Falaise and Pascal Ledoux
- Journal of Clinical Medicine 2021, TOUCH® Prosthesis for Thumb Carpometacarpal Joint Osteoarthritis: A Prospective Case Series, Stefan M. Froschauer 1, 2, 3, *, Matthias Holzbauer 1, 2, 3, *, Julian A. Mihalic 1, 2, 3 and Oskar Kwasny 1, 2, 3

7. Suggested profile and training for users

- Physician – orthopaedist, traumatologist, surgeon
- Must have experience with implantation of the trapeziometacarpal joint

8. Reference to any harmonised standards and common specifications applied

1/ REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (EU) 2017/745 of 5 April 2017, on medical devices, changes to Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009, and on repealing Council Directive 90/385/EEC and 93/42/EEC.

2/ As amended by: Regulation of the European Parliament and of the Council (EU) 2020/561 of 23 April 2020, 02017R0745 – CS – 24/04/2020 – 001.001 – 1.

3/ Document of the Medical Device Coordination Group MDCG 2020-7, Template of the Post-market Clinical Follow-up Plan (PMCF), Guide for manufacturers and notified bodies, April 2020.

4/ ČSN EN ISO 14971 – Medical devices – Application of risk management to medical devices (85 5231), June 2020.

5/ ČSN EN ISO 14155:2021 – Clinical trials of medical devices for human use – Good clinical practice

6/ ČSN EN ISO 14630 (852905):2013 – Non-active surgical implants – General requirements

7/ ČSN EN ISO 21534 (852909):2009 – Non-active surgical implants – Implants for joint replacement – Special requirements

8/ ČSN EN ISO 16061 (852940):2021 – Instruments used with non-active surgical implants – General requirements

9/ ČSN EN ISO 20417 (850004):2021 – Medical devices – Information provided by the manufacturer

10/ ČSN EN 556-1 (855255):2002 – Sterilisation of medical devices – Requirements for medical devices labelled as "STERILE" - Part 1: Requirements for medical devices sterilised in the end packaging

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11/ ČSN EN ISO 11135 (855252):2015 – Sterilisation of healthcare products – Sterilisation with ethylene oxide – Requirements for development, validation and continuous management of the sterilisation procedure for medical devices
12/ ČSN EN ISO 15223-1 (850005):2022 – Medical devices – Label marks, labelling and information provided with medical devices – Part 1: General requirements
13/ ČSN EN ISO 13485 ed. 2 (855001):2017 – Medical devices – Quality management systems – Requirements for regulatory purposes
14/ ČSN EN ISO 5832-1 (856358):2020 – Surgical implants – Metal materials – Part 1: Moulded stainless steel
15/ ČSN EN ISO 5832-2 (856358):2018 – Surgical implants – Metal materials – Part 2: Pure titanium
16/ ČSN EN ISO 5832-3 (856358):2021 – Surgical implants – Metal materials – Part 3: Alloy of titanium, aluminium 6 and vanadium 4 for moulding
17/ ISO 5832-12:2019 - Implants for surgery — Metallic materials — Part 12: Wrought cobalt-chromium-molybdenum alloy
18/ ISO 5834-2:2019–ed.5.0 - Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 2: Moulded forms
19/ ISO 5833:2002-ed.2.0 - Implants for surgery — Acrylic resin cements
20/ ISO 13779-2:2018-ed.3.0 - Implants for surgery - Hydroxyapatite - Part 2: Thermally sprayed coatings of hydroxyapatite
21/ ASTM F1147-05(2017)e1 – Standard Test Method For Tension Testing Of Calcium Phosphate And Metallic Coatings
22/ ČSN EN ISO 11607-1 (855280):2020 – Packaging for medical devices sterilised in the end packaging - Part 1: Requirements for materials, sterile barrier systems and packaging systems
23/ ČSN EN ISO 11607-2 (855280):2020 – Packaging for finally sterilised medical devices – Part 2: Validation of requirements for the moulding process, sealing and assembly
24/ GAP analyses of standards, internal document of Beznoska s.r.o., dated 15/10/ – 22/10/2021
25/ DESIGN DOSSIER 7 – internal document of BEZNOSKA, s.r.o.
26/ RM12 – risk management – internal document of BEZNOSKA, s.r.o.
27/ RM General – risk management – internal document of BEZNOSKA, s.r.o.
28/ TOS-4.19.-01, PP-4.19.-01-01 – internal document of BEZNOSKA, s.r.o.

9. Revision history

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
2	7.12.20232	Changes based on comments – see the F18A NR form – Report on Assessment of MD Technical Documentation of 18/01/2023 and physician 3EC	❑ Yes Validation language: ❑ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52(4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
			❑ Yes

			Validation language: ❑ No

Drafted by: Ing. Milan Sekerka

On: 07/02/2023

Revision: 2

The Summary of Safety and Clinical Performance intended for patients is provided below.

Summary of Safety and Clinical Performance Intended for Patients

Document revision: 2
Date of issue: 07/02/2023

The purpose of this Summary of Safety and Clinical Performance (SSCP) is to provide public access to the updated summary of the key aspects of safety and clinical performance of the device. The information provided below is intended for patients or non-professional general public. A more detailed summary of safety and clinical performance data intended for medical professionals is provided in the first part of this document.

The SSCP is not intended to provide general advice concerning treatment of a specific medical problem. If you have any questions concerning your medical condition or the use of the device in your situation, please consult your physician. This SSCP is not to replace the information sheet for the implant or the instructions for use providing information on safe use of the device.

1. Device identification and general information

- Trade name of MD

Number	Trade name
1	ELIS - DŘÍK NECEM., T, 1
	ELiS - Cementless stem, T, 1
	ELiS - Zementfreier Schaft, T, 1
	ELiS - Driek necem., T, 1
	ELiS - Vástago sin cementar, T, 1
	ELiS - Haste não ciment., T, 1
	ELiS - Бесцементная ножка, T, 1
	ELiS - Безцементна ніжка, T, 1
2	ELIS - DŘÍK NECEM., T, 2
	ELiS - Cementless stem, T, 2
	ELiS - Zementfreier Schaft, T, 2
	ELiS - Driek necem., T, 2
	ELiS - Vástago sin cementar, T, 2
	ELiS - Haste não ciment., T, 2
	ELiS - Бесцементная ножка, T, 2
	ELiS - Безцементна ніжка, T, 2
3	ELIS - DŘÍK NECEM., T, 3
	ELiS - Cementless stem, T, 3
	ELiS - Zementfreier Schaft, T, 3
	ELiS - Driek necem., T, 3
	ELiS - Vástago sin cementar, T, 3
	ELiS - Haste não ciment., T, 3
	ELiS - Бесцементная ножка, T, 3
	ELiS - Безцементна ніжка, T, 3
4	ELIS - DŘÍK NECEM., T, 4

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	ELiS - Cementless stem, T, 4
	ELiS - Zementfreier Schaft, T, 4
	ELiS - Driek necem., T, 4
	ELiS - Vástago sin cementar, T, 4
	ELiS - Haste não ciment., T, 4
	ELiS - Бесцементная ножка, T, 4
	ELiS - Безцементна ніжка, T, 4
5	ELIS - DŘÍK NECEM., T, 5
	ELiS - Cementless stem, T, 5
	ELiS - Zementfreier Schaft, T, 5
	ELiS - Driek necem., T, 5
	ELiS - Vástago sin cementar, T, 5
	ELiS - Vástago sin cementar, T, 5
	ELiS - Бесцементная ножка, T/II (Ti+ГА), 5
	ELiS - Безцементна ніжка, T/II (Ti та ГА), 5
6	ELIS - DŘÍK NECEM., T/II (TI+HA), 1
	ELiS - Cementless stem, T/II (Ti+HA), 1
	ELiS - Zementfreier Schaft, T/II (Ti+HA), 1
	ELiS - Driek necem., T/II (Ti+HA), 1
	ELiS - Vástago sin cementar, T/II (Ti+HA), 1
	ELiS - Haste não ciment., T/II (Ti + HA), 1
	ELiS - Бесцементная ножка, T/II (Ti+ГА), 1
	ELiS - Безцементна ніжка, T/II (Ti та ГА), 1
7	ELIS - DŘÍK NECEM., T/II (TI+HA), 2
	ELiS - Cementless stem, T/II (Ti+HA), 2
	ELiS - Zementfreier Schaft, T/II (Ti+HA),
	ELiS - Driek necem., T/II (Ti+HA), 2
	ELiS - Vástago sin cementar, T/II (Ti+HA), 2
	ELiS - Haste não ciment., T/II (Ti + HA), 2
	ELiS - Бесцементная ножка, T/II (Ti+ГА), 2
	ELiS - Безцементна ніжка, T/II (Ti та ГА), 2
8	ELIS - DŘÍK NECEM., T/II (TI+HA), 3
	ELiS - Cementless stem, T/II (Ti+HA), 3
	ELiS - Zementfreier Schaft, T/II (Ti+HA), 3
	ELiS - Driek necem., T/II (Ti+HA), 3
	ELiS - Vástago sin cementar, T/II (Ti+HA), 3
	ELiS - Haste não ciment., T/II (Ti + HA), 3
	ELiS - Бесцементная ножка, T/II (Ti+ГА), 3
	ELiS - Безцементна ніжка, T/II (Ti та ГА), 2
9	ELIS - DŘÍK NECEM., T/II (TI+HA), 4
	ELiS - Cementless stem, T/II (Ti+HA), 4
	ELiS - Zementfreier Schaft, T/II (Ti+HA), 4
	ELiS - Driek necem., T/II (Ti+HA), 4
	ELiS - Vástago sin cementar, T/II (Ti+HA), 4
	ELiS - Haste não ciment., T/II (Ti + HA), 4
	ELiS - Бесцементная ножка, T/II (Ti+ГА), 4
	ELiS - Безцементна ніжка, T/II (Ti та ГА), 4

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10	ELIS - DŘÍK NECEM., T/II (TI+HA), 5
	ELiS - Cementless stem, T/II (Ti+HA), 5
	ELiS - Zementfreier Schaft, T/II (Ti+HA), 5
	ELiS - Driek necem., T/II (Ti+HA), 5
	ELiS - Vástago sin cementar, T/II (Ti+HA), 5
	ELiS - Haste não ciment., T/II (Ti + HA), 5
	ELiS - Бесцементная ножка, T/II (Ti+ГА), 5
	ELiS - Безцементна ніжка, T/II (Ti та ГА), 5
11	ELIS - DŘÍK NECEM. (KN), 1
	ELiS - Cementless stem, (CC), 1
	ELiS - Zementfreier Schaft, (CC), 1
	ELiS - Driek necem., (CC), 1
	ELiS - Vástago sin cementar, (CC), 1
	ELiS - Haste não ciment., (CC), 1
	ELiS - Бесцементная ножка, (CC), 1
	ELiS - Безцементна ніжка, (CC), 1
12	ELIS - DŘÍK NECEM. (KN), 1+
	ELiS - Cementless stem, (CC), 1+
	ELiS - Zementfreier Schaft, (CC), 1+
	ELiS - Driek necem., (CC), 1+
	ELiS - Vástago sin cementar, (CC), 1+
	ELiS - Haste não ciment., (CC), 1+
	ELiS - Бесцементная ножка, (CC), 1+
	ELiS - Безцементна ніжка, (CC), 1+
13	ELIS - DŘÍK NECEM. (KN), 2
	ELiS - Cementless stem, (CC), 2
	ELiS - Zementfreier Schaft, (CC), 2
	ELiS - Driek necem., (CC), 2
	ELiS - Vástago sin cementar, (CC), 2
	ELiS - Haste não ciment., (CC), 2
	ELiS - Бесцементная ножка, (CC), 2
	ELiS - Безцементна ніжка, (CC), 2
14	ELIS - DŘÍK NECEM. (KN), 2+
	ELiS - Cementless stem, (CC), 2+
	ELiS - Zementfreier Schaft, (CC), 2+
	ELiS - Driek necem., (CC), 2+
	ELiS - Vástago sin cementar, (CC), 2+
	ELiS - Haste não ciment., (CC), 2+
	ELiS - Бесцементная ножка, (CC), 2+
	ELiS - Безцементна ніжка, (CC), 2+
15	ELIS - DŘÍK NECEM. (KN), 3
	ELiS - Cementless stem, (CC), 3
	ELiS - Zementfreier Schaft, (CC), 3
	ELiS - Driek necem., (CC), 3
	ELiS - Haste não ciment., (CC), 3
	ELiS - Бесцементная ножка, (CC), 3
	ELiS - Безцементна ніжка, (CC), 3

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16	ELIS - DŘÍK NECEM. (KN), 4
	ELiS - Cementless stem, (CC), 4
	ELiS - Zementfreier Schaft, (CC), 4
	ELiS - Driek necem., (CC), 4
	ELiS - Vástago sin cementar, (CC), 4
	ELiS - Haste não ciment., (CC), 4
	ELiS - Бесцементна ніжка, (CC), 4
	ELiS — Бесцементна ніжка, (CC), 4
17	ELIS - DŘÍK NECEM. (KN), 5
	ELiS - Cementless stem, (CC), 5
	ELiS - Zementfreier Schaft, (CC), 5
	ELiS - Driek necem., (CC), 5
	ELiS - Vástago sin cementar, (CC), 5
	ELiS - Haste não ciment., (CC), 5
	ELiS - Бесцементная ножка, (CC), 5
	ELiS - Безцементна ніжка, (CC), 5
18	ELIS - DŘÍK NECEM. (KN), 5+
	ELiS - Cementless stem, (CC), 5+
	ELiS - Zementfreier Schaft, (CC), 5+
	ELiS - Driek necem., (CC), 5+
	ELiS - Vástago sin cementar, (CC), 5+
	ELiS - Haste não ciment., (CC), 5+
	ELiS - Бесцементная ножка, (CC), 5+
	ELiS - Безцементна ніжка, (CC), 5+
Number	**Trade name**
19	ELIS - KRČEK PŘÍMÝ, T/II, 5/12, S
	ELiS - Straight neck, T/II, 5/12, S
	ELiS - Hals, gerade, T/II, 5/12, S
	ELiS - Krčok priamy, T/II, 5/12, S
	ELiS - Cuello recto, T/II, 5/12, S
	ELiS - Colo reto, T/II, 5/12, S
	ELiS - Прямая шейка, T/II, 5/12, S
	ELiS - Пряма шийка, T/II, 5/12, S
20	ELIS - KRČEK PŘÍMÝ, T/II, 5/14, M
	ELiS - Straight neck, T/II, 5/14, M
	ELiS - Hals, gerade, T/II, 5/14, M
	ELiS - Krčok priamy, T/II, 5/14, M
	ELiS - Cuello recto, T/II, 5/14, M
	ELiS - Colo reto, T/II, 5/14, M
	ELiS - Прямая шейка, T/II, 5/14, M
	ELiS - Пряма шийка, T/II, 5/14, M
21	ELIS - KRČEK PŘÍMÝ, T/II, 5/16, L
	ELiS - Straight neck, T/II, 5/16, L
	ELiS - Hals, gerade, T/II, 5/16, L
	ELiS - Krčok priamy, T/II, 5/16, L
	ELiS - Cuello recto, T/II, 5/16, L

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	ELiS - Colo reto, T/II, 5/16, L
	ELiS - Прямая шейка, T/II, 5/16, L
	ELiS - Пряма шийка, T/II, 5/16, L
22	ELIS - KRČEK PŘÍMÝ, T/II, 5/18, XL
	ELiS - Straight neck, T/II, 5/18, XL
	ELiS - Hals, gerade, T/II, 5/18, XL
	ELiS - Krčok priamy, T/II, 5/18, XL
	ELiS - Cuello recto, T/II, 5/18, XL
	ELiS - Colo reto, T/II, 5/18, XL
	ELiS - Прямая шейка, T/II, 5/18, XL
	ELiS - Пряма шийка, T/II, 5/18, XL
23	ELIS - KRČEK VALGÓZNÍ 15°, T/II, 5/12, S
	ELiS - Valgus neck 15°, T/II, 5/12, S
	ELiS - Hals, Valgus 15°, T/II, 5/12, S
	ELiS - Krčok valgózny 15°, T/II, 5/12, S
	ELiS - Cuello recto, T/II, 5/18, XL
	ELiS - Colo valgo 15°, T/II, 5/12, S
	ELiS - Шейка вальгусная 15°, T/II, 5/12, S
	ELiS - Шийка вальгусна 15°, T/II, 5/12, S
24	ELIS - KRČEK VALGÓZNÍ 15°, T/II, 5/14, M
	ELiS - Valgus neck 15°, T/II, 5/14, M
	ELiS - Hals, Valgus 15°, T/II, 5/14, M
	ELiS - Krčok valgózny 15°, T/II, 5/14, M
	ELiS - Cuello valgus de 15°, T/II, 5/14, M
	ELiS - Colo valgo 15°, T/II, 5/14, M
	ELiS - Шейка вальгусная 15°, T/II, 5/14, M
	ELiS - Шийка вальгусна 15°, T/II, 5/14, M
25	ELIS - KRČEK VALGÓZNÍ 15°, T/II, 5/16, L
	ELiS - Valgus neck 15°, T/II, 5/16, L
	ELiS - Hals, Valgus 15°, T/II, 5/16, L
	ELiS - Krčok valgózny 15°, T/II, 5/16, L
	ELiS - Cuello valgus de 15°, T/II, 5/16, M
	ELiS - Colo valgo 15°, T/II, 5/16, L
	ELiS - Шейка вальгусная 15°, T/II, 5/16, L
	ELiS - Шийка вальгусна 15°, T/II, 5/16, L
26	ELIS - KRČEK VALGÓZNÍ 15°, T/II, 5/18, XL
	ELiS - Valgus neck 15°, T/II, 5/18, XL
	ELiS - Hals, Valgus 15°, T/II, 5/18, XL
	ELiS - Krčok valgózny 15°, T/II, 5/18, XL
	ELiS - Cuello valgus de 15°, T/II, 5/18, XL
	ELiS - Colo valgo 15°, T/II, 5/18, XL
	ELiS - Шейка вальгусная 15°, T/II, 5/18, XL
	ELiS - Шийка вальгусна 15°, T/II, 5/18, XL
27	ELIS - KRČEK VALG. 15°/ANTE-R, 5/12
	ELiS - Valgus neck 15°/Ante-R, 5/12
	ELiS - Hals, Valgus 15°/Ante-R, 5/12
	ELiS - Krčok valgózny 15°/Ante-R, 5/12

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	ELiS - Colo valgo 15°/Ante-R, 5/12
	ELiS - Colo valgo 15°/Ante-R, 5/12
	ELiS - Шейка вальгусная 15°/Ante-R, 5/12
	ELiS - Шийка вальгусна 15°/Ante-R, 5/12
28	ELIS - KRČEK VALG. 15°/ANTE-R, 5/14
	ELiS - Valgus neck 15°/Ante-R, 5/14
	ELiS - Hals, Valgus 15°/Ante-R, 5/14
	ELiS - Krčok valgózny 15°/Ante-R, 5/14
	ELiS - Cuello valgus de 15°/Ante-R, 5/14
	ELiS - Colo valgo 15°/Ante-R, 5/14
	ELiS - Шейка вальгусная 15°/Ante-R, 5/14
	ELiS - Шийка вальгусна 15°/Ante-R, 5/14
29	ELIS - KRČEK VALG. 15°/ANTE-R, 5/16
	ELiS - Valgus neck 15°/Ante-R, 5/16
	ELiS - Hals, Valgus 15°/Ante-R, 5/16
	ELiS - Krčok valgózny 15°/Ante-R, 5/16
	ELiS - Cuello valgus de 15°/Ante-L, 5/16
	ELiS - Colo valgo 15°/Ante-L, 5/16
	ELiS - Шейка вальгусная 15°/Ante-R, 5/16
	ELiS - Шейка вальгусная 15°/Ante-R, 5/16
30	ELIS - KRČEK VALG. 15°/ANTE-R, 5/18
	ELiS - Valgus neck 15°/Ante-R, 5/18
	ELiS - Hals, Valgus 15°/Ante-R, 5/18
	ELiS - Krčok valgózny 15°/Ante-R, 5/18
	ELiS - Cuello valgus de 15°/Ante-R, 5/18
	ELiS - Colo valgo 15°/Ante-R, 5/18
	ELiS - Шейка вальгусная 15°/Ante-R, 5/18
	ELiS - Шийка вальгусна 15°/Ante-R, 5/18
31	ELIS - KRČEK VALG. 15°/ANTE-L, 5/12
	ELiS - Valgus neck 15°/Ante-L, 5/12
	ELiS - Hals, Valgus 15°/Ante-L, 5/12
	ELiS - Krčok valgózny 15°/Ante-L, 5/12
	ELiS - Cuello valgus de 15°/Ante-L, 5/12
	ELiS - Colo valgo 15°/Ante-L, 5/12
	ELiS - Шейка вальгусная 15°/Ante-L, 5/12
	ELiS - Шийка вальгусна 15°/Ante-L, 5/12
32	ELIS - KRČEK VALG. 15°/ANTE-L, 5/14
	ELiS - Valgus neck 15°/Ante-L, 5/14
	ELiS - Krčok valgózny 15°/Ante-L, 5/14
	ELiS - Hals, Valgus 15°/Ante-L, 5/14
	ELiS - Cuello valgus de 15°/Ante-L, 5/14
	ELiS - Colo valgo 15°/Ante-L, 5/14
	ELiS - Шейка вальгусная 15°/Ante-L, 5/14
	ELiS - Шийка вальгусна 15°/Ante-L, 5/14
33	ELIS - KRČEK VALG. 15°/ANTE-L, 5/16
	ELiS - Valgus neck 15°/Ante-L, 5/16
	ELiS - Hals, Valgus 15°/Ante-L, 5/16

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	ELiS - Krčok valgózny 15°/Ante-L, 5/16
	ELiS - Cuello valgus de 15°/Ante-L, 5/16
	ELiS - Colo valgo 15°/Ante-L, 5/16
	ELiS - Шейка вальгусная 15°/Ante-L, 5/16
	ELiS - Шийка вальгусна 15°/Ante-L, 5/16
34	ELIS - KRČEK VALG. 15°/ANTE-L, 5/18
	ELiS - Valgus neck 15°/Ante-L, 5/18
	ELiS - Hals, Valgus 15°/Ante-L, 5/18
	ELiS - Krčok valgózny 15°/Ante-L, 5/18
	ELiS - Cuello valgus de 15°/Ante-L, 5/18
	ELiS - Colo valgo 15°/Ante-L, 5/18
	ELiS - Шейка вальгусная 15°/Ante-L, 5/18
	ELiS - Шийка вальгусна 15°/Ante-L, 5/18
Number	**Trade name**
35	ELIS - DM - KRČEK PŘÍMÝ, 7.7/12
	ELiS - DM - Straight neck, 7.7/12
	ELiS - DM - Hals, gerade, 7.7/12
	ELiS - DM - Krčok priamy, 7.7/12
	ELiS - DM - Cuello recto, 7.7/12
	ELiS - DM - Cuello recto, 7.7/12
	ELiS - DM - Cuello recto, 7.7/12
	ELiS - DM - Пряма шийка, 7.7/12
36	ELIS - DM - KRČEK PŘÍMÝ, 7.7/14
	ELiS - DM - Straight neck, 7.7/14
	ELiS - DM - Hals, gerade, 7.7/14
	ELiS - DM - Krčok priamy, 7.7/14
	ELiS - DM - Cuello valgus de 15°, 7.7/14
	ELiS - DM - Colo reto, 7.7/14
	ELiS - DM - Прямая шейка, 7.7/14
	ELiS - DM - Пряма шийка, 7.7/14
37	ELIS - DM - KRČEK PŘÍMÝ, 7.7/16
	ELiS - DM - Straight neck, 7.7/16
	ELiS - DM - Hals, gerade, 7.7/16
	ELiS - DM - Krčok priamy, 7.7/16
	ELiS - DM - Cuello valgus de 15°, 7.7/16
	ELiS - DM - Colo reto, 7.7/16
	ELiS - DM - Прямая шейка, 7.7/16
	ELiS - DM - Пряма шийка, 7.7/16
38	ELIS - DM - KRČEK PŘÍMÝ, 7.7/18
	ELiS - DM - Straight neck, 7.7/18
	ELiS - DM - Hals, gerade, 7.7/18
	ELiS - DM - Krčok priamy, 7.7/18
	ELiS - DM - Cuello valgus de 15°, 7.7/18
	ELiS - DM - Colo reto, 7.7/18
	ELiS - DM - Прямая шейка, 7.7/18
	ELiS - DM - Пряма шийка, 7.7/18

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39	ELIS - DM - KRČEK VALG. 15°, 7.7/12
	ELiS - DM - Valgus neck 15°, 7.7/12
	ELiS - DM - Hals, Valgus 15°, 7.7/12
	ELiS - DM - Krčok valgózny 15°, 7.7/12
	ELiS - DM - Cuello valgus de 15°, 7.7/12
	ELiS - DM - Cuello valgus de 15°, 7.7/12
	ELiS - DM — Шейка вальгусная 15°, 7.7/12
	ELiS - DM — Шийка вальгусна 15°, 7.7/12
40	ELIS - DM - KRČEK VALG. 15°, 7.7/14
	ELiS - DM - Hals, Valgus 15°, 7.7/14
	ELiS - DM - Krčok valgózny 15°, 7.7/14
	ELiS - DM - Cuello valgus de 15°, 7.7/14
	ELiS - DM - Cuello valgus de 15°, 7.7/14
	ELiS – DM - Шейка вальгусная 15°, 7.7/14
	ELiS - DM - Шийка вальгусна 15°, 7.7/14
	ELiS - DM - Hals, Valgus 15°, 7.7/14
41	ELIS - DM - KRČEK VALG. 15°, 7.7/16
	ELiS - DM - Hals, Valgus 15°, 7.7/16
	ELiS - DM - Krčok valgózny 15°, 7.7/16
	ELiS - DM - Cuello valgus de 15°, 7.7/16
	ELiS - DM - Cuello valgus de 15°, 7.7/16
	ELiS - DM - Шейка вальгусная 15°, 7.7/16
	ELiS - DM - Шийка вальгусна 15°, 7.7/16
	ELiS - DM - Hals, Valgus 15°, 7.7/16
42	ELIS - DM - KRČEK VALG. 15°, 7.7/18
	ELiS - DM - Hals, Valgus 15°, 7.7/18
	ELiS - DM - Krčok valgózny 15°, 7.7/18
	ELiS - DM - Cuello valgus de 15°, 7.7/18
	ELiS - DM - Cuello valgus de 15°, 7.7/18
	ELiS - DM - Шейка вальгусная 15°, 7.7/18
	ELiS - DM - Шийка вальгусна 15°, 7.7/18
	ELiS - DM - Hals, Valgus 15°, 7.7/18
43	ELIS - DM - KRČEK VALG. 15°/ANTE-L, 7.7/12
	ELiS - DM - Valgus neck 15°/Ante-L, 7.7/12
	ELiS - DM - Hals, Valgus 15°/Ante-L, 7.7/12
	ELiS - DM - Krčok valgózny 15°/Ante-L, 7.7/12
	ELiS - DM - Cuello valgus de 15°/Ante-L, 7.7/12
	ELiS - DM - Cuello valgus de 15°/Ante-L, 7.7/12
	ELiS - DM - Шейка вальгусная 15°/Ante-L, 7.7/12
	ELiS - DM - Шийка вальгусна 15°/Ante-L, 7.7/12
44	ELIS - DM - KRČEK VALG. 15°/ANTE-L, 7.7/14
	ELiS - DM - Valgus neck 15°/Ante-L, 7.7/14
	ELiS - DM - Hals, Valgus 15°/Ante-L, 7.7/14
	ELiS - DM - Krčok valgózny 15°/Ante-L, 7.7/14
	ELiS - DM - Cuello valgus de 15°/Ante-L, 7.7/14
	ELiS - DM - Cuello valgus de 15°/Ante-L, 7.7/14
	ELiS - DM - Шейка вальгусная 15°/Ante-L, 7.7/14

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	ELiS - DM - Шийка вальгусна 15°/Ante-L, 7.7/14
45	ELIS - DM - KRČEK VALG. 15°/ANTE-L, 7.7/16
	ELiS - DM - Valgus neck 15°/Ante-L, 7.7/16
	ELiS - DM - Hals, Valgus 15°/Ante-L, 7.7/16
	ELiS - DM - Krčok valgózny 15°/Ante-L, 7.7/16
	ELiS - DM - Cuello valgus de 15°/Ante-L, 7.7/16
	ELiS - DM - Cuello valgus de 15°/Ante-L, 7.7/16
	ELiS - DM - Шейка вальгусная 15°/Ante-L, 7.7/16
	ELiS - DM - Шийка вальгусна 15°/Ante-L, 7.7/16
46	ELIS - DM - KRČEK VALG. 15°/ANTE-L, 7.7/18
	ELiS - DM - Valgus neck 15°/Ante-L, 7.7/18
	ELiS - DM - Hals, Valgus 15°/Ante-L, 7.7/18
	ELiS - DM - Krčok valgózny 15°/Ante-L, 7.7/18
	ELiS - DM - Cuello valgus de 15°/Ante-L, 7.7/18
	ELiS - DM - Cuello valgus de 15°/Ante-L, 7.7/18
	ELiS - DM - Шейка вальгусная 15°/Ante-L, 7.7/18
	ELiS - DM - Шийка вальгусна 15°/Ante-L, 7.7/18
47	ELIS - DM - KRČEK VALG. 15°/ANTE-R, 7.7/12
	ELiS - DM - Valgus neck 15°/Ante-R, 7.7/12
	ELiS - DM - Hals, Valgus 15°/Ante-R, 7.7/12
	ELiS - DM - Krčok valgózny 15°/Ante-R, 7.7/12
	ELiS - DM - Cuello valgus de 15°/Ante-R, 7.7/12
	ELiS - DM - Cuello valgus de 15°/Ante-R, 7.7/12
	ELiS - DM - Шейка вальгусная 15°/Ante-R, 7.7/12
	ELiS - DM - Шийка вальгусна 15°/Ante-R, 7.7/12
48	ELIS - DM - KRČEK VALG. 15°/ANTE-R, 7.7/14
	ELiS - DM - Valgus neck 15°/Ante-R, 7.7/14
	ELiS - DM - Hals, Valgus 15°/Ante-R, 7.7/14
	ELiS - DM - Krčok valgózny 15°/Ante-R, 7.7/14
	ELiS - DM - Cuello valgus de 15°/Ante-R, 7.7/14
	ELiS - DM - Cuello valgus de 15°/Ante-R, 7.7/14
	ELiS - DM - Шейка вальгусная 15°/Ante-R, 7.7/14
	ELiS - DM - Шийка вальгусна 15°/Ante-R, 7.7/14
49	ELIS - DM - KRČEK VALG. 15°/ANTE-R, 7.7/16
	ELiS - DM - Valgus neck 15°/Ante-R, 7.7/16
	ELiS - DM - Hals, Valgus 15°/Ante-R, 7.7/16
	ELiS - DM - Krčok valgózny 15°/Ante-R, 7.7/16
	ELiS - DM - Cuello valgus de 15°/Ante-R, 7.7/16
	ELiS - DM - Cuello valgus de 15°/Ante-R, 7.7/16
	ELiS - DM - Шейка вальгусная 15°/Ante-R, 7.7/16
	ELiS - DM - Шийка вальгусна 15°/Ante-R, 7.7/16
50	ELIS - DM - KRČEK VALG. 15°/ANTE-R, 7.7/18
	ELiS - DM - Valgus neck 15°/Ante-R, 7.7/18
	ELiS - DM - Hals, Valgus 15°/Ante-R, 7.7/18
	ELiS - DM - Krčok valgózny 15°/Ante-R, 7.7/18
	ELiS - DM - Cuello valgus de 15°/Ante-R, 7.7/18
	ELiS - DM - Cuello valgus de 15°/Ante-R, 7.7/18

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	ELiS - DM - Шейка вальгусная 15°/Ante-R, 7.7/18
	ELiS - DM - Шейка вальгусная 15°/Ante-R, 7.7/18
Number	**Trade name**
51	ELIS - PLÁŠŤ JAMKY NECEM., T/III, D9
	ELiS - Cementless cup, T/III, D9
	ELiS - Zementfreie Pfanne, T/III, D9
	ELiS - Plášť jamky necem., T/III, D9
	ELiS - Cotilo sin cemento, T/III, D9
	ELiS - Taça não ciment., T/III, D9
	ELiS - Бесцементная чашка, T/III, D9
	ELiS - Безцементна чашка, T/III, D9
52	ELIS - PLÁŠŤ JAMKY NECEM., T/III, D10
	ELiS - Cementless cup, T/III, D10
	ELiS - Zementfreie Pfanne, T/III, D10
	ELiS - Plášť jamky necem., T/III, D10
	ELiS - Cotilo sin cemento, T/III, D10
	ELiS - Taça não ciment., T/III, D10
	ELiS - Бесцементная чашка, T/III, D10
	ELiS - Безцементна чашка, T/III, D10
Number	**Trade name**
53	ELIS - SPHERE - PLÁŠŤ JAMKY NECEM. (KN), D9
	ELiS - Sphere - Cementless cup (CC), D9
	ELiS - Sphere - Zementfreie Pfanne (CC), D9
	ELiS - Sphere - Plášť jamky necem. (CC), D9
	ELiS - Sphere - Cotilo sin cemento (CC), D9
	ELiS - Sphere - Taça não ciment. (CC), D9
	ELiS - Sphere - Бесцементная чашка (CC), D9
	ELiS - Sphere - Безцементна чашка (CC), D9
54	ELIS - SPHERE - PLÁŠŤ JAMKY NECEM. (KN), D10
	ELiS - Sphere - Cementless cup (CC), D10
	ELiS - Sphere - Zementfreie Pfanne (CC), D10
	ELiS - Sphere - Plášť jamky necem. (CC), D10
	ELiS - Sphere - Cotilo sin cemento (CC), D10
	ELiS - Sphere - Taça não ciment. (CC), D10
	ELiS - Sphere - Бесцементная чашка (CC), D10
	ELiS - Sphere - Безцементна чашка (CC), D10
55	ELIS - VLOŽKA, T/III, PRO HLAVIČKU D5
	ELiS - Insert, T/III, for head D5
	ELiS - Einsatz, T/III, für Kopf D5
	ELiS - Vložka, T/III, na hlavičku D5
	ELiS - Inserto, T/III, para cabeza D5
	ELiS - Inserção, T/III, p/ cabeça D5
	ELiS - Вставка, T/III, под головку D5
	ELiS - Вставка, T/III, для головки D5
56	ELIS - SPHERE, DM - PLÁŠŤ JAMKY NECEM. (KN), D9

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	ELiS - Sphere, DM - Cementless cup (CC), D9
	ELiS - Sphere, DM - Zementfreie Pfanne (CC), D9
	ELiS - Sphere, DM - Plášť jamky necem. (CC), D9
	ELiS - Sphere, DM - Cotilo sin cemento (CC), D9
	ELiS - Sphere, DM - Taça não ciment. (CC), D9
	ELiS - Sphere, DM - Бесцементная чашка (CC), D9
	ELiS - Sphere, DM - Безцементна чашка (CC), D9
57	ELIS - SPHERE, DM - PLÁŠŤ JAMKY NECEM. (KN), D10
	ELiS - Sphere, DM - Cementless cup (CC), D10
	ELiS - Sphere, DM - Zementfreie Pfanne (CC), D10
	ELiS - Sphere, DM - Plášť jamky necem. (CC), D10
	ELiS - Sphere, DM - Cotilo sin cemento (CC), D10
	ELiS - Sphere, DM - Taça não ciment. (CC), D10
	ELiS - Sphere, DM - Бесцементная чашка (CC), D10
	ELiS - Sphere, DM - Безцементна чашка (CC), D10
58	ELIS - KONOS, DM - PLÁŠŤ JAMKY NECEM. (KN), D9
	ELiS - Konos, DM - Cementless cup (CC), D9
	ELiS - Konos, DM - Zementfreie Pfanne (CC), D9
	ELiS - Konos, DM - Plášť jamky necem. (CC), D9
	ELiS - Konos, DM - Cotilo sin cemento (CC), D9
	ELiS - Konos, DM - Taça não ciment. (CC), D9
	ELiS - Konos, DM - Бесцементная чашка (CC), D9
	ELiS - Konos, DM - Безцементна чашка (CC), D9
59	ELIS - KONOS, DM - PLÁŠŤ JAMKY NECEM. (KN), D10
	ELiS - Konos, DM - Cementless cup (CC), D10
	ELiS - Konos, DM - Zementfreie Pfanne (CC), D10
	ELiS - Konos, DM - Plášť jamky necem. (CC), D10
	ELiS - Konos, DM - Cotilo sin cemento (CC), D10
	ELiS - Konos, DM - Taça não ciment. (CC), D10
	ELiS - Konos, DM - Бесцементная чашка (CC), D10
	ELiS - Konos, DM - Безцементна чашка (CC), D10

Number	**Trade name**
60	ELIS - JAMKA CEM. S OFFSETEM, T/II, 5/10
	ELiS - Trapezium repl., TR, 16/17, D11
	ELiS - Trapeziumersatz, TR, 16/17, D11
	ELiS - Náhrada trapézia, TR, 16/17, D11
	ELiS - Reemplazo de trapecio, TR, 16/17, D11
	ELiS - Repl. de trapézio, TR, 16/17, D11
	ELiS - Протез кости-трапеции, TR, 16/17, D11
	ELiS - Протез кістки-трапеції, TR, 16/17, D11
61	ELIS - SPHERE - JAMKA CEM., 5/10
	ELiS - Sphere - Cemented cup, 5/10
	ELiS - Sphere - Zementierte Pfanne, 5/10
	ELiS - Sphere - Jamka cem., 5/10
	ELiS - Sphere - Jamka cem., 5/10
	ELiS - Sphere - Taça ciment., 5/10

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	ELiS - Sphere - Цементная чашка, 5/10
	ELiS - Sphere - Цементна чашка, 5/10
Number	**Trade name**
62	ELIS - NÁHRADA TRAPÉZIA, TR, 14/15, D9
	ELiS - Trapezium repl., TR, 14/15, D9
	ELiS - Trapeziumersatz, TR, 14/15, D9
	ELiS - Náhrada trapézia, TR, 14/15, D9
	ELiS - Reemplazo de trapecio, TR, 14/15, D9
	ELiS - Repl. de trapézio, TR, 14/15, D9
	ELiS - Протез кости-трапеции, TR, 14/15, D9
	ELiS - Протез кістки-трапеції, TR, 14/15, D9
63	ELIS - NÁHRADA TRAPÉZIA, TR, 15/16, D10
	ELiS - Trapezium repl., TR, 15/16, D10
	ELiS - Trapeziumersatz, TR, 15/16, D10
	ELiS - Náhrada trapézia, TR, 15/16, D10
	ELiS - Reemplazo de trapecio, TR, 15/16, D10
	ELiS - Repl. de trapézio, TR, 15/16, D10
	ELiS - Протез кости-трапеции, TR, 15/16, D10
	ELiS - Протез кістки-трапеції, TR, 15/16, D10
64	ELIS - NÁHRADA TRAPÉZIA, TR, 16/17, D11
	ELiS - Trapezium repl., TR, 16/17, D11
	ELiS - Trapeziumersatz, TR, 16/17, D11
	ELiS - Náhrada trapézia, TR, 16/17, D11
	ELiS - Reemplazo de trapecio, TR, 16/17, D11
	ELiS - Repl. de trapézio, TR, 16/17, D11
	ELiS - Протез кости-трапеции, TR, 16/17, D11
	ELiS - Протез кістки-трапеції, TR, 16/17, D11
Number	**Trade name**
65	ELIS - VLOŽKA NÁHR. TRAPÉZIA, TR, 9/5
	ELiS - Trapezium insert, TR, 9/5
	ELiS - Trapeziumeinsatz, TR, 9/5
	ELiS - Vložka náhr. trapézia, TR, 9/5
	ELiS - Inserto de trapecio, TR, 9/5
	ELiS - Inserção de trapézio, TR, 9/5
	ELiS - Вставка для кости-трапеции, TR, 9/5
	ELiS - Вставка для кістки-трапеції, TR, 9/5
66	ELIS - VLOŽKA NÁHR. TRAPÉZIA, TR, 10/5
	ELiS - Trapezium insert, TR, 10/5
	ELiS - Trapeziumeinsatz, TR, 10/5
	ELiS - Vložka náhr. trapézia, TR, 10/5
	ELiS - Inserto de trapecio, TR, 10/5
	ELiS - Inserção de trapézio, TR, 10/5
	ELiS - Вставка для кости-трапеции, TR, 10/5
	ELiS - Вставка для кістки-трапеції, TR, 10/5
67	ELIS - VLOŽKA NÁHR. TRAPÉZIA, TR, 11/5

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	ELiS - Trapezium insert, TR, 11/5
	ELiS - Trapeziumeinsatz, TR, 11/5
	ELiS - Vložka náhr. trapézia, TR, 11/5
	ELiS - Inserto de trapecio, TR, 11/5
	ELiS - Inserção de trapézio, TR, 11/5
	ELiS - Вставка для кости-трапеции, TR, 11/5
	ELiS - Вставка для кістки-трапеції, TR, 11/5

- Manufacturer; name and address

BEZNOSKA, s.r.o.

Dělnická 2727,
272 01 Kladno – Kročehlavy, Czech Republic

- Basic UDI-DI

859260207001FZ

- Year when the first certificate (CE) was issued covering the device

The MDs listed above in the table with trade names obtained certification gradually as follows:

  - 2012 - DNV - Certificate No. 24538, 13/04/2013
  - 2015 - EZÚ - MED 150068, 07/04/2015
  - 2019 - EZÚ - MED 190044, 12/12/2019
  - 2020 - EZÚ - MED 200056, 07/05/2021

2. Intended use of the device

- Intended use
  - The implants are intended as replacement of the trapeziometacarpal joint.

- Indications and target populations
  - Indications:

    Primary and secondary rhizarthrosis resistant to conservative treatment; rheumatoid arthritis is also a relative indication (not applicable to the trapezium bone replacement); Eaton-Littler II-IV X-ray criterion; unfixed Z deformity of the thumb in the MCP joint.

- Target group:

  Age – adult population 18+, men, women;
  Nationality - irrelevant.

- **Contraindications**
  - Young, highly active patient (growth in progress);
  - X-ray Eaton-Littler IV (not applicable to the trapezium bone replacement);
  - Rigid Z deformity of the thumb in the MCP joint is relative contraindication (can be resolved at two time points or simultaneously with TEP of the TMC joint;
  - Small trapezium (not applicable to the trapezium bone replacement);
  - Dysplastic trapezium (Kapandji>140°) (not applicable to the trapezium bone replacement);
  - Severe osteoporosis;
  - Allergies (Ti, Al, V, Co, Cr, Mo, UHMWPE, HAp, bone cement);
  - Specific and non-specific inflammatory disease;
  - Tumours in the relevant location;
  - Patient's inability to cooperate following the surgery.

3. Device description

- **Description of the device and materials/substances that come into contact with the patient's tissues**
  - **Replacement of the trapeziometacarpal joint (TEP of the TMC joint)** consisting of a stem, neck and cup is intended for primo implantation in the case of damaged articulating parts of the trapezium and metacarpal bones that can no longer be addressed by conservative treatment. In special cases, the implant can also be used for revision surgery after a TEP failure.
    This configuration of the trapeziometacarpal joint replacement always consists of three parts – a metacarpal stem, neck with a head, and cementless cup placed in the trapezium bone (cup + PE insert) or a cemented cup.
    The total replacement of the trapeziometacarpal joint consisting of a stem, neck and trapezium replacement is intended for revision surgery, when the cup cannot be anchored in the trapezium due to the existing defects. Furthermore, it is intended for severe arthrosis requiring removal of the bone (trapezium).
    This configuration of the trapeziometacarpal joint replacement always consists of three parts – a metacarpal stem, neck with a head with a diameter of 5 (mm) and trapezium replacement (body + PE insert).

Fig. 01 - ELiS – Cementless stem - type T

Fig. 02 - ELiS - Cementless stem - type T/II (Ti+HA)

Fig. 03 - ELiS - Cementless stem (CC)

Fig. 04 - ELiS - Straight neck

Fig. 05 - ELiS - Valgus neck

Fig. 06 - ELiS - DM - Straight neck

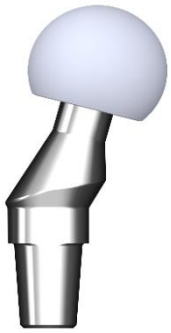

Fig. 07 - ELiS - DM - Valgus neck

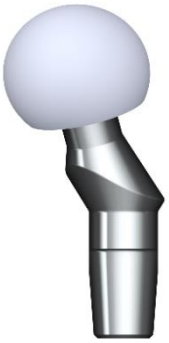

Fig. 08 - ELiS - DM - Valgus neck/ante

Fig. 09 - EliS - Cementless cup T/II

Fig. 10 - ELiS - Sphere - Cup

Fig. 11 - ELiS - PE insert

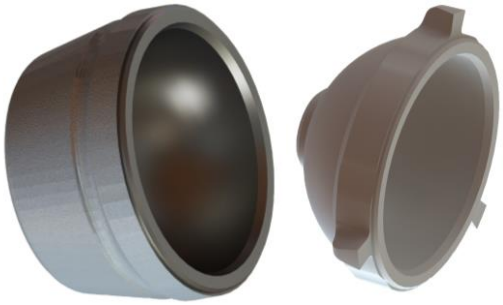

Fig. 12 - ELiS - Konos and Sphere

Fig. 13 - ELiS - Sphere, DM – Cup

Fig. 14 - ELiS – Sphere, DM – Cup

Fig. 15 - ELiS - Cemented cup T/II

Fig. 16 - ELIS - Sphere - Cemented cup

Fig. 17 - Trapezium replacement

Fig. 18 - Trapezium replacement body

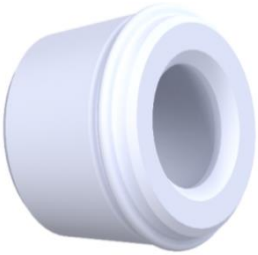

Fig. 19 - Trapezium insert

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- **Materials/substances that come into contact with the patient's tissues**
  - ČSN EN ISO 5832-1 (856358):2020 – Implants for surgery - Metallic materials - Part 1: Wrought stainless steel;
  - ČSN EN ISO 5832-2 (856358):2018 – Implants for surgery - Metallic materials - Part 2: Unalloyed titanium;
  - ČSN EN ISO 5832-3 (856358):2021 – Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy;
  - ISO 5832-12:2019 – Implants for surgery - Metallic materials - Part 12: Wrought cobalt-chromium-molybdenum alloy;
  - ISO 5834-2:2019-ed.5.0 – Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 2: Moulded forms;
  - ISO 5833:2002-ed.2.0 – Implants for surgery — Acrylic resin cements;
  - ISO 13779-2:2018-ed.3.0 – Implants for surgery — Hydroxyapatite — Part 2: Thermally sprayed coatings of hydroxyapatite;
  - In double sterile packaging (SBS – Sterile Barrier System) – the MD is in contact with elements determining its precise position made of materials (DuPont™ Tyvek®, Tyvek 1073B and Tyvek 1059B by Nelipak® Healthcare Packaging) or is in contact with sterilisation packaging material STERIKING®
  - In short-term contact with the MD during implantation – instruments specified by the manufacturer of the MD (such as introduction tools, stoppers and extractors) and MDs for hand protection during surgery at the operating theatre.

  The device does not contain any medicines and is not made with materials of animal origin.

- Surgical – endoprosthesis with a competition MD, arthrodesis, interposition arthroplasty (trapeziectomy with plastic surgery using a tendon).

  The device achieves the intended effect by replacing the function of the trapeziometacarpal joint on the hand as its total replacement, which is configured as a set of devices and implanted in the patient's joint capsule.

- **Description of any accessories**

  The medical device (MD) consists of modular connecting parts (MDs) for configuration in a set and instruments for the application of the MD.
  The medical device does not contain any accessories in the sense of the definition pursuant to the MDR.

4. Risks and warnings

If you believe that you are experiencing side effects associated with the device or its use, or if you have any safety concerns, please contact your physician. This document does not replace necessary consultation with a physician.

- **How potential risks are controlled and managed**

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Potential risks are controlled by the notified body 3EC international a.s., which assesses annual documents drafted on the medical device (MD). These are documents drafted and managed in accordance with (EU) 2017/745 (MDR) and the guide for manufacturers and notified bodies MDCG 2019-9: August 2019, MDCG 2022-2021: December 2022, MDCG 2020-8: April 2020, MDCG 2020-7: April 2020, ČSN EN ISO 14971:2020 – Medical devices – Application of risk management to medical devices. Specifically, these are the Summary of Safety and Clinical Performance (SSCP) of the MD, Periodic Safety Update Report (PSUR) for the MD, Report on the Assessment of Post-market Clinical Follow-up (PMS including PMCF information), Risk Management and Report on Risk Management Review pursuant to the standard ČSN EN ISO 14971:2020.

- **Residual risks and adverse effects**
  - Residual risks: Risk of MD failure, if the user fails to observe the requirements for use listed in the instructions for use.
- Potential adverse complications associated with surgery:
  - During surgery
    - Damage to the venous and nervous structures
    - Iatrogenic bone damage, sometimes even fracture
  - After surgery
    - Cardiovascular conditions, such as thromboembolic disease, deep phlebothrombosis, MI, postoperative haematoma
    - Wound healing disorders, infections
    - Loosening of the entire total replacement or its component, deformation or breakage of a component, flexion contracture, shortened limb
- **Warnings and precautions**
  - The patient consents to the surgery and the associated risks – see the section on adverse complications;
  - The patient needs to be mentally capable of understanding the significance of the surgery and observe the postoperative regimen;
  - The patient needs to be aware of the limitations presented by the implant;
  - Not using the implant in patients with documented allergies to or intolerance of metals (Ti, Al, V, Co, Cr, Mo, UHMWPE, HAp, bone cement);
  - Patients receiving the trapeziometacarpal joint replacement must be informed that the lifespan of the implant depends on their weight and the level of their activity;
  - The patient needs to be aware of the limitations presented by the implant (observe the strict postoperative regimen during the first three months – limit stress on the limb and avoid any vibration);
  - The patient needs to be warned that their new implant may only be put under limited stress until the bones have healed entirely;
  - We recommend consultation with a specialist in the case of any unexpected changes (any changes to the medical condition (also in the case of pregnancy for women)) that may concern the implant;

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- Based on the available information, patients with implants by BEZNOSKA, s.r.o. may undergo magnetic resonance imaging with a static magnetic field up to 3T, but no sooner than 6 weeks after the implantation and if no signs of loosening are present (see the Declaration of Admissibility of Magnetic Resonance Imaging + methodical sheet for examining patient with metal implants with MR + contraindications and risks of examination using MR – the information is available at https://www.beznoska.cz/pro-pacienty/nejcastejsi-otazky);

- **Summary of all field safety corrective measures (FSCA, including FSN), if applicable**

  No indication of the need for preventative or corrective safety measures has been concluded from the information obtained from post-market follow-up.

5. Summary of clinical evaluation and post-market follow-up

- **Clinical context of the device**

  The medical device has undergone three clinical trials, which were conducted in 2010, 2014 and 2020 pursuant to the Act on Medical Devices valid at the time (123/2000 Coll., 268/2014 Coll.) and overseen by the State Institute for Drug Control (Státní ústav pro kontrolu léčiv, SÚKL ČR). The group of patients from the clinical trial in 2010 and 2014 was regularly followed up at annual intervals for years (follow-up) according to the clinical trial schedule. The percentage of completed follow-up for 5 years was 100 %. There were no study limitations, and there was no shortcoming in the device or replacement of the device associated with safety and/or effectiveness of the device during the study and the follow-up (5 years). The follow-up for the clinical trial completed in 2020 will continue until 2025. The three-year follow-up confirms that the percentage of follow-up completion after 3 years was 100 %. There were no study limitations, and there was no shortcoming in the device or replacement of the device associated with safety and/or effectiveness of the device during the study and the follow-up (3 years).

  The medical devices have been marketed since 2012, and the third generation of the trapeziometacarpal joint is currently on the market. No adverse events, complaints or quality complaints have been reported throughout the period of sale. Several thousand products have been sold in the Czech Republic and abroad.

- **Clinical evidence for CE certification**

  Each generation of the trapeziometacarpal joint underwent CE certification. The first generation of the trapeziometacarpal joint was tested in the clinical trial in 2011. The functional parameters of the implant were verified in full, and the achievement of these parameters was confirmed during the follow-up. The implant design significantly improved the functioning of the trapeziometacarpal joint, reducing the VAS, DASH value. The second generation underwent clinical testing in 2014. The functional parameters of the implant were verified in full, and the achievement of these parameters was confirmed during the follow-up. The implant design significantly improved the functioning of the trapeziometacarpal joint, reducing the VAS, DASH value. The third generation underwent clinical testing in 2020. The functional parameters of the implant were verified in full, and the achievement of these parameters was confirmed during the follow-up. The implant design significantly improved the functioning of the trapeziometacarpal joint, reducing the VAS (pain), DASH (questionnaire on difficulties and ability to perform certain tasks) value, the key pinch and hand grip strength improved.

- **Safety**

  Prior to implantation of the MD, patients are negatively affected mostly by the poor grip strength in the thumb, reduced mobility, pain in the locomotor system,

and the use of analgesics, which is eliminated in most cases after implantation of the MD.

The implantation of the MD, which is part of the surgery to perform total replacement of the trapeziometacarpal joint, brings positive impact on the clinical outcome and significant improvement in the patient's quality of life compared to the preoperative condition in the parameters listed below.

According to literature research, replacement of the trapeziometacarpal joint currently achieves the best results in the treatment of rhizarthrosis and the associated risks are relatively mild. This is also supported by the results of the completed post-market follow-up, during which no complaint, quality complaint or adverse event occurred. Nonetheless, potential risks associated with implantation and long-term use of the replacement cannot be ruled out. Based on the available data, the benefit of the trapeziometacarpal joint (significant improvement in the mobility of the thumb joint, reduced pain) significantly outweighs the potential residual risk of the possible failure of the implant, even in the case of a different method of treating rhizarthrosis.

The methods and procedures determined by the manufacturer for active gathering and assessment of clinical data arising from the use of the medical device are evaluated regularly, at least once a year, to confirm long-term safety and clinical effectiveness, and potential improvement measures are adopted as needed.

6. Possible diagnostic or therapeutic alternatives

If you consider different treatment methods, we recommend that you consult your physician, as they can consider your individual situation.

- **General description of therapeutic alternatives**
  - Conservative treatment (local transdermal treatment with drugs or patches) Treatment of joints with medication includes the use of products reducing pain and mitigating inflammation. This type of treatment is not entirely safe in many cases and causes problems in other organs, mainly in the digestive tract, liver, kidneys and heart. Local therapy and physiotherapy only provide temporary relief and sometimes no relief can be achieved with these means.
  - Surgical – endoprosthesis with a competition MD, arthrodesis, interposition arthroplasty (trapeziectomy with plastic surgery using a tendon).

7. Proposed instructions for users

- Instruction for use of the MD no. 012
- Surgery manual "Total replacement of the trapeziometacarpal joint".