

INSTRUMENT SET - MEGASYSTEM-C[®] TUMOR AND REVISION SURGERY

Device Description and Details

The following section provides an overview of the general information of the instrument set. This includes the used materials and coatings, the item-codes, GMDN- and UMDNS-Codes and the intended use of the instrument set. Furthermore it offers details on the EU classification and other general information.

1 System

Instrument Set for Megasytem-C[®] Tumor and Revision Surgery

2 Manufacturer

Waldemar Link GmbH & Co. KG

Barkhausenweg 10

D-22339 Hamburg

3 Intended use


Instruments for Tumor and Revision Surgery

4 Used materials and coatings

4.1 Materials

Stainless steel (1.4021)	acc. to DIN EN 10088-1
Stainless steel (1.4301)	acc. to DIN EN 10088-1
Stainless steel (1.4305)	acc. to DIN EN 10088-1
Stainless steel (1.4112)	acc. to DIN EN 10088-3
Stainless steel (1.4057)	acc. to DIN EN 10088-3
Stainless steel (1.4310)	acc. to DIN EN 10088-3, AISI 302, ASTM 899
Stainless steel (1.4028)	acc. to ISO 7153-1
Stainless steel (1.4404)	acc. to ISO 7153-1
Stainless steel (1.4542)	acc. to ISO 7153-1
Stainless steel (1.4441)	acc. to ISO 5832-1
CoCrMo	acc. to ISO 5832-12
Polyamid PA12 (nature)	acc. to DIN EN 15860
Polypropylen-Homopolymerisat (PP-H)	acc. to DIN EN 15860, ASTM D4101
TiAl6V4	acc. to ISO 5832-3
Radel/PPSU Life Science Grade (LSG)	
Aluminium Alloy (Al 99,5) (Tray)	acc. (EN AIW-1050A)
Silicone rubber	


5 Device Details

Container complete – Tapered Reamers 100 mm							
No	Item no.	Description	Size	GMDN Code	UMDNS Code	Material	Class. EU acc. to 93/42/EEC
	15-8710/01	Container, complete, Tapered Reamers 100 mm		Consisting of:			
	05-2001/03	N11 Standard container, empty		13730 Sterilization container	13-730 Sterilization container	1.4301 Al 99,5	I
	15-8711/01	Tray					
1	15-8711/01	Tray, empty		13730 Sterilization container	13-730 Sterilization container	1.4301 Al 99,5	I

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2	16-5100/12	Tapered Reamer	Ø12 mm, 100 mm	45115 Medullary canal orthopaedic reamer, rigid	13-297 Orthopaedic reamer	1.4542	I
3	16-5100/13	Tapered Reamer	Ø13 mm, 100mm				
4	16-5100/14	Tapered Reamer	Ø14 mm, 100 mm				
5	16-5100/15	Tapered Reamer	Ø15 mm, 100 mm				
6	16-5100/16	Tapered Reamer	Ø16 mm, 100 mm				
7	16-5100/17	Tapered Reamer	Ø17 mm, 100 mm				
8	16-5100/18	Tapered Reamer	Ø18 mm, 100 mm				
9	16-5100/19	Tapered Reamer	Ø19 mm, 100 mm				
10	16-5100/20	Tapered Reamer	Ø20 mm, 100 mm				
11	16-5100/21	Tapered Reamer	Ø21 mm, 100 mm				
12	16-5100/22	Tapered Reamer	Ø22 mm, 100 mm				
13	16-5100/23	Tapered Reamer	Ø23 mm, 100 mm				
14	16-5100/24	Tapered Reamer	Ø24 mm, 100 mm				


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Container complete – Tapered Reamers 130 mm							
No	Item no.	Description	Size	GMDN Code	UMDNS Code	Material	Class. EU acc. to 93/42/EEC
	15-8720/01	Container, complete, Tapered Reamers 130mm		Consisting of:			
	05-2001/03	N11 Standard container, empty		13730 Sterilization container	13-730 Sterilization container	1.4301 Al 99,5	I
	15-8721/01	Tray					
1	15-8721/01	Tray, empty		13730 Sterilization container	13-730 Sterilization container	1.4301 Al 99,5	I
2	16-5130/12	Tapered Reamer	Ø12 mm, 130 mm	45115 Medullary canal orthopaedic reamer, rigid	13-297 Orthopaedic reamer	1.4542	I
3	16-5130/13	Tapered Reamer	Ø13 mm, 130 mm				
4	16-5130/14	Tapered Reamer	Ø14 mm, 130 mm				
5	16-5130/15	Tapered Reamer	Ø15 mm, 130 mm				

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6	16-5130/16	Tapered Reamer	Ø16 mm, 130 mm	45115 Medullary canal orthopaedic reamer, rigid	13-297 Orthopaedic reamer	1.4542	I
7	16-5130/17	Tapered Reamer	Ø17 mm, 130 mm				
8	16-5130/18	Tapered Reamer	Ø18 mm, 130 mm				
9	16-5130/19	Tapered Reamer	Ø19 mm, 130 mm				
10	16-5130/20	Tapered Reamer	Ø20 mm, 130 mm				
11	16-5130/21	Tapered Reamer	Ø21 mm, 130 mm				
12	16-5130/22	Tapered Reamer	Ø22 mm, 130 mm				
13	16-5130/23	Tapered Reamer	Ø23 mm, 130 mm				
14	16-5130/24	Tapered Reamer	Ø24 mm, 130 mm				

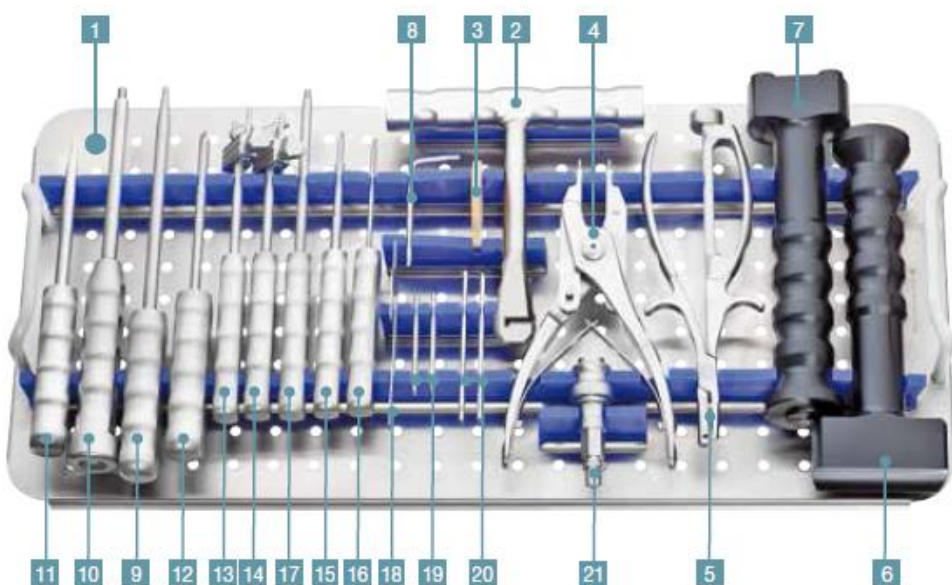
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Container complete – Tapered Reamers 160 mm							
No	Item no.	Description	Size	GMDN Code	UMDNS Code	Material	Class. EU acc. to 93/42/EEC
	15-8730/01	Container, complete, Tapered Reamers 160mm		Consisting of:			
	05-2001/03	N11 Standard container, empty		13730 Sterilization container	13-730 Sterilization container	1.4301 Al 99,5	I
	15-8731/01	Tray					
1	15-8731/01	Tray, empty		13730 Sterilization container	13-730 Sterilization container	1.4301 Al 99,5	I
2	16-5160/12	Tapered Reamer	Ø12 mm, 160 mm	45115 Medullary canal orthopaedic reamer, rigid	13-297 Orthopaedic reamer	1.4542	I
3	16-5160/13	Tapered Reamer	Ø13 mm, 160 mm				
4	16-5160/14	Tapered Reamer	Ø14 mm, 160 mm				
5	16-5160/15	Tapered Reamer	Ø15 mm, 160 mm				

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6	16-5160/16	Tapered Reamer	Ø16 mm, 160 mm	45115 Medullary canal orthopaedic reamer, rigid	13-297 Orthopaedic reamer	1.4542	I
7	16-5160/17	Tapered Reamer	Ø17 mm, 160 mm				
8	16-5160/18	Tapered Reamer	Ø18 mm, 160 mm				
9	16-5160/19	Tapered Reamer	Ø19 mm, 160 mm				
10	16-5160/20	Tapered Reamer	Ø20 mm, 160 mm				
11	16-5160/21	Tapered Reamer	Ø21 mm, 160 mm				
12	16-5160/22	Tapered Reamer	Ø22 mm, 160 mm				
13	16-5160/23	Tapered Reamer	Ø23 mm, 160 mm				
14	16-5160/24	Tapered Reamer	Ø24 mm, 160 mm				

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Container complete – General Instruments I							
No	Item no.	Description	Size	GMDN Code	UMDNS Code	Material	Class. EU acc. to 93/42/EEC
	15-8740/01	Container, complete, General Instruments I		Consisting of:			
	05-2001/03	N11 Standard container, empty		13730 Sterilization container	13-730 Sterilization container	1.4301 Al 99,5	I
	15-8741/01	Tray					
1	15-8741/01	Tray, empty		13730 Sterilization container	13-730 Sterilization container	1.4301 Al 99,5	I
2	15-6053/00	T-Handle, with Hudson fitting		47829 Surgical instrument handle	13-180 Orthopaedic prosthesis implantation instrument	1.4305 1.4112	I

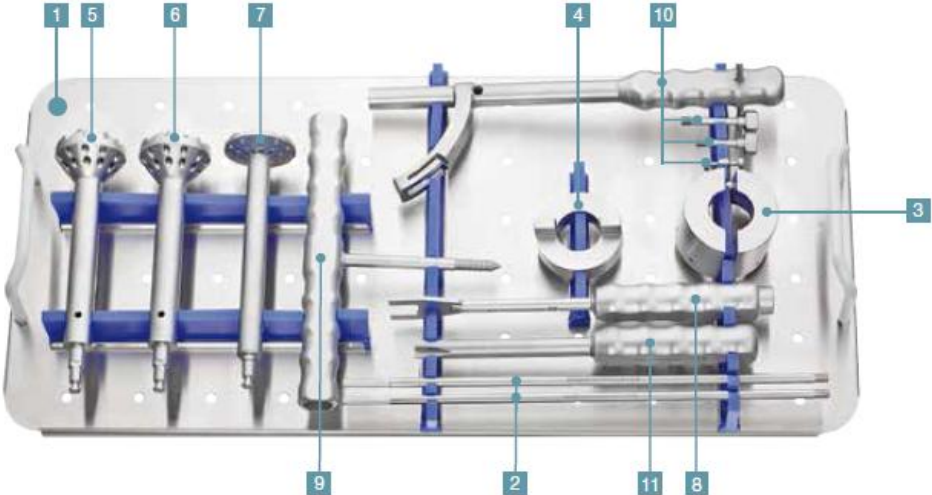
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3	16-3203/00	Impaction plate	13180 Orthopaedic prosthesis implantation instrument	13-180 Orthopaedic prosthesis implantation instrument	PP-H	I
4	16-0020/01	Connecting / Disconnecting forceps 175 mm	11798 Utility forceps, reusable	11-798 Orthopaedic forceps	1.4021 1.4305 1.4310	I
5	317-586	Extraction forceps 210 mm	11798 Utility forceps, reusable	11-798 Orthopaedic forceps	1.4021	I
6	317-646/01	Grooved driver for femoral components	12696 Orthopaedic implant inserter/ extractor	13-180 Orthopaedic prosthesis implantation instrument	PP-H	I
7	16-0018/02	Grooved driver for tibial components	12696 Orthopaedic implant inserter/ extractor	13-180 Orthopaedic prosthesis implantation instrument	PP-H	I
8	16-0116/01	Hex screwdriver 2.5 mm	33968 Surgical screwdriver	13-517 Screwdriver, bone	1.4021	I
9	64-8008/02	Hex screwdriver 3.5 mm, 250 mm	33968 Surgical screwdriver	13-517 Screwdriver, bone	1.4021 1.4305	I
10	15-8516/45	Driver extractor 365 mm	12696 Orthopaedic implant inserter/ extractor	13-180 Orthopaedic prosthesis implantation instrument	1.4021 1.4305	I
11	322-145/01	Screwdriver 8 mm, 210 mm	33968 Surgical screwdriver	13-517 Screwdriver, bone	1.4021 1.4305	I
12	317-658/01	Bone awl 215 mm	15275 Awl	13-297 Orthopaedic reamer	1.4021 1.4305	I

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13	15-8035/02	Insertion instrument for PE (S,M,L)	32865 Orthopaedic implant driver	13-180 Orthopaedic prosthesis implantation instrument	1.4305 1.4021	I
14	15-8035/03	Insertion instrument for PE (XS)	32865 Orthopaedic implant driver	13-180 Orthopaedic prosthesis implantation instrument	1.4305 1.4021	I
15	10-5373/01	Hex screwdriver 2.5 mm, 180mm	33968 Surgical screwdriver	13-517 Screwdriver, bone	1.4021 1.4305	I
16	15-2546	Hex screwdriver 2.0 mm, 175mm				
17	16-0017/01	Separate rod M5 220 mm	13180 Orthopaedic prosthesis implantation instrument	13-180 Orthopaedic prosthesis implantation instrument	1.4305	I
18	317-607/50	Cutting template	47815 Orthopaedic implant aiming/ guiding block	13-425 Router, Bone Cutting	1.4310	I
19	317-585/65	Wire pins Ø 3 mm, 65 mm	13180 Orthopaedic prosthesis implantation instrument	13-368 Fixation pins	1.4441	I
20	317-585/95	Wire pins Ø 3 mm, 95 mm				
21	16-3283/01	Adapter Hudson/Jacobs	47847 Orthopaedic implant/ instrument adaptor, reusable	11-726 Adapter / Connector	1.4305	I
22	16-3284/00	Adapter Hudson/AO			1.4057	
23	16-3285/00	Adapter Hudson/Harris			1.4305	

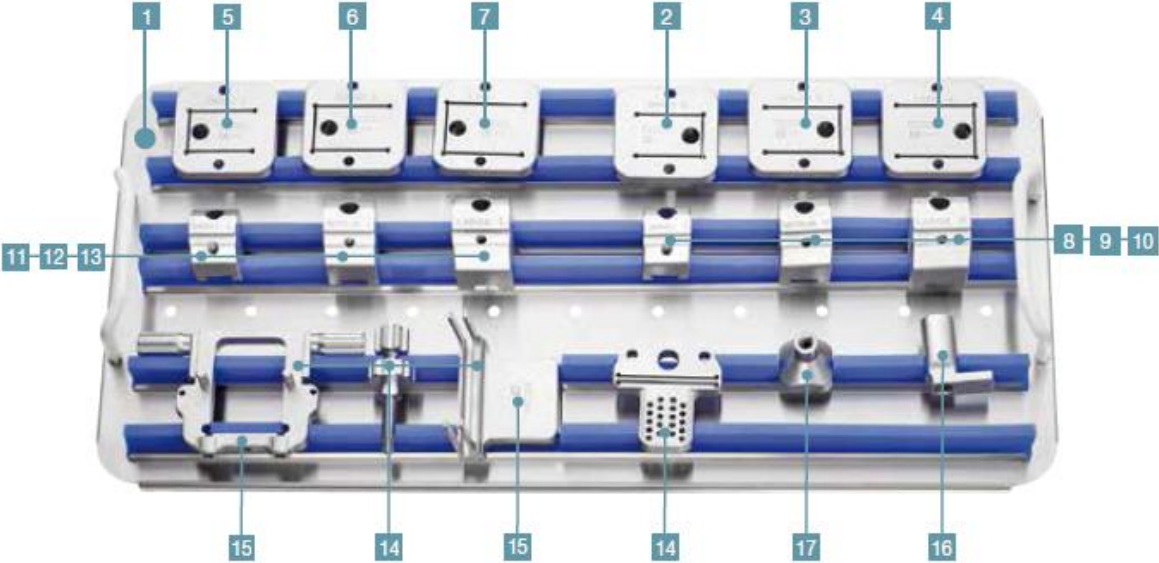
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Container complete – General Instruments II							
No	Item no.	Description	Size	GMDN Code	UMDNS Code	Material	Class. EU acc. to 93/42/EEC
	15-8750/01	Container, complete, General Instruments II		Consisting of:			
	05-2001/03	N11 Standard container, empty		13730 Sterilization container	13-730 Sterilization container	1.4301 Al 99,5	I
	15-8751/01	Tray					
1	15-8751/01	Tray, empty		13730 Sterilization container	13-730 Sterilization container	1.4301 Al 99,5	I
2	16-3235/00	Guide rod		13180 Orthopaedic prosthesis implantation instrument	11-927 Guide	1.4404	I
3	16-3236/00	Adapter ring		47847 Orthopaedic implant/ instrument adaptor, reusable	11-726 Adapter/ Connector	1.4404	I

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4	16-3237/00	Saw guide	47815 Orthopaedic implant aiming/ guiding block	13-425 Router, Bone Cutting	1.4542	I
5	16-3204/18	Step reamer Ø 18 mm	45114 Bone-resection orthopaedic reamer	17-995 Orthopaedic reamer	1.4542	Ila
6	16-3204/24	Step reamer Ø 24 mm	45114 Bone-resection orthopaedic reamer	17-995 Orthopaedic reamer	1.4542	Ila
7	16-3205/30	Reamer Ø 30 mm, 85 mm	45114 Bone-resection orthopaedic reamer	17-995 Orthopaedic reamer	1.4542	Ila
8	15-8516/41	Separator 235 mm	12696 Orthopaedic implant inserter/ extractor	13-180 Orthopaedic prosthesis implantation instrument	1.4021 1.4305	I
9	15-8506/52	Distraction instrument	12696 Orthopaedic implant inserter/ extractor	13-180 Orthopaedic prosthesis implantation instrument	1.4021 1.4305	I
10	131-379/00	Insertion instrument for neck segments	32865 Orthopaedic implant driver	13-180 Orthopaedic prosthesis implantation instrument	1.4021 1.4305	I
11	16-3290/00	Cross slot screwdriver 210 mm	33968 Surgical screwdriver, reusable	13-517 Screwdriver, bone	1.4021 1.4305	I

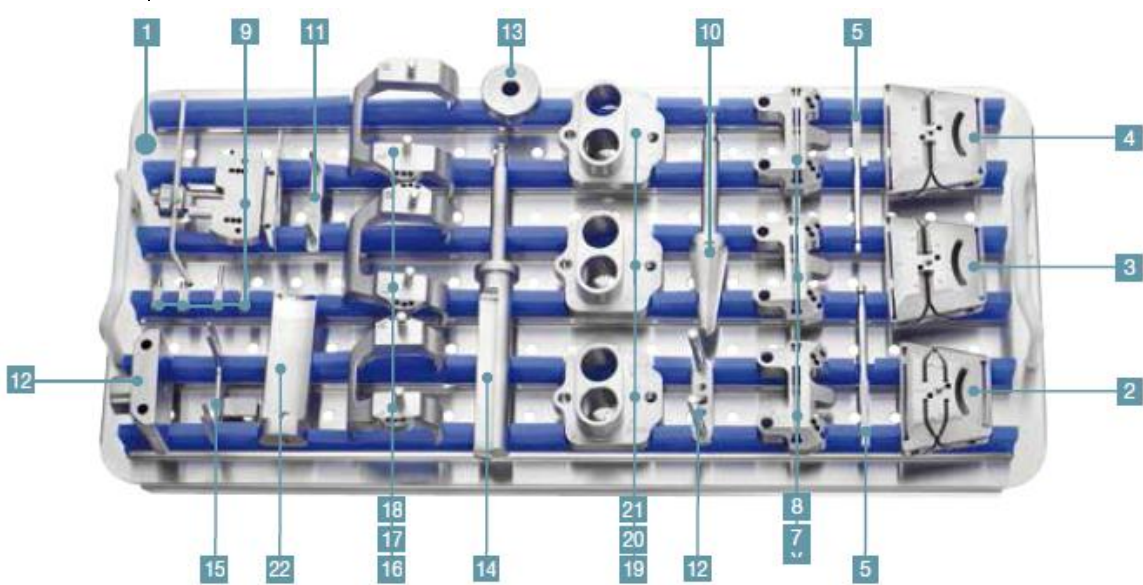
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Container complete – Femur I							
No	Item no.	Description	Size	GMDN Code	UMDNS Code	Material	Class. EU acc. to 93/42/EEC
	15-8760/01	Container, complete, Femur I		Consisting of:			
	05-2001/03	N11 Standard container, empty		13730 Sterilization container	13-730 Sterilization container	1.4301 Al 99,5	I
	15-8761/01	Tray 					
1	15-8761/01	Tray, empty		13730 Sterilization container	13-730 Sterilization container	1.4301 Al 99,5	I
2	16-3221/01	Saw attachment	small S right	47815 Orthopaedic implant aiming/ guiding block	13-425 Router, Bone Cutting	1.4028	I
3	16-3223/01		medium M right				
4	16-3225/01		large L right				

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5	16-3221/02	Saw attachment	small S left	47815 Orthopaedic implant aiming/ guiding block	13-425 Router, Bone Cutting	1.4028	I
6	16-3223/02		medium M left				
7	16-3225/02		large L left				
8	16-3261/01	Femoral trial box	small S right	58481 Femoral stem trial prosthesis	17-704 Trial prosthesis, Hip, Joint	1.4404	I
9	16-3263/01		medium M right				
10	16-3265/01		large L right				
11	16-3261/02		small S left				
12	16-3263/02		medium M left				
13	16-3265/02		large L left				
14	16-3277/00		Revision cutting block				
15	16-3278/00	Revision alignment gauge	47815 Orthopaedic implant aiming/ guiding block	11-927 Guide	1.4542 1.4404	I	
16	16-3282/00	Alignment instrument	13180 Orthopaedic prosthesis implantation instrument	16-223 Positioning guide	1.4404	I	
17	16-3271/00	Adapter	47847 Orthopaedic implant/ instrument adaptor, reusable	11-726 Adapter/ Connector	1.4542	I	

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Container complete – Femur II							
No	Item no.	Description	Size	GMDN Code	UMDNS Code	Material	Class. EU acc. to 93/42/EEC
	15-8770/01	Container, complete, Femur II		Consisting of:			
	05-2002/03	N11 Standard container, empty		13730 Sterilization container	13-730 Sterilization container	1.4301 Al 99,5	I
	15-8771/01	Tray					
1	15-8771/01	Tray, empty		13730 Sterilization container	13-730 Sterilization container	1.4301 Al 99,5	I
2	16-3250/02	Femur cutting block for chamfer cuts	size 2	47815 Orthopaedic implant aiming/ guiding block	13-425 Router, Bone Cutting	1.4112 1.4404 1.4542	I
3	16-3250/03		size 3				
4	16-3250/04		size 4				

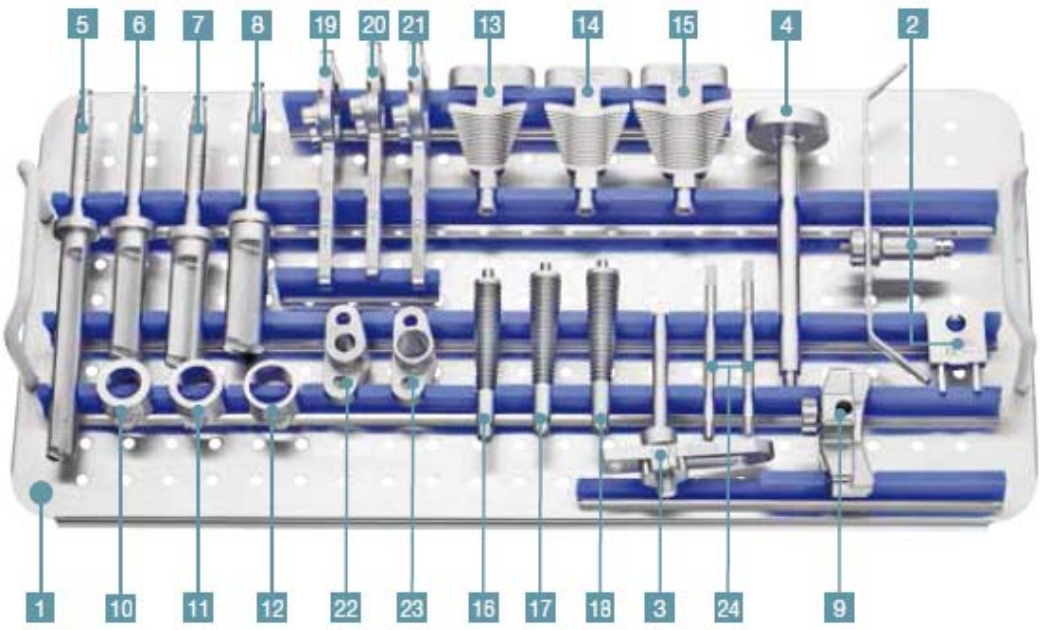
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5	317-802/58	Alignment rod for epicondyles100 mm		47815 Orthopaedic implant aiming/ guiding block	16-223 Positioning guide	1.4404	I
6	16-3228/02	Femur cutting block for distal cut	size 2	47815 Orthopaedic implant aiming/ guiding block	13-425 Router, Bone Cutting	1.4112 Silicone	I
7	16-3228/03		size 3				
8	16-3228/04		size 4				
9	16-3276/00	Alignment instrument for determination of external rotation (5 parts)		47815 Orthopaedic implant aiming/ guiding block	16-223 Positioning guide	1.4404 1.4112 1.4301 1.4542	I
10	16-3202/00	Drill		32390 Surgical drill, reusable	17-995 Orthopaedic drill	1.4542	Ila
11	317-802/36	Dove tail adapter		47815 Orthopaedic implant aiming/ guiding block	11-726 Adapter/ Connector	1.4542	I
12	16-3275/00	Alignment instrument for valgus angulation (2 parts)		47815 Orthopaedic implant aiming/ guiding block	16-223 Positioning guide	1.4542 1.4404 1.4021	I
13	16-3281/00	Center sleeve		47815 Orthopaedic implant aiming/ guiding block	11-927 Guide	1.4542	I
14	16-3206/20	Drill with stop Ø 20 mm		32390 Surgical drill, reusable	17-995 Orthopaedic drill	1.4542	Ila
15	16-3279/00	Holding clamp		13180 Orthopaedic prosthesis implantation instrument	16-771 Clamp	1.4404	I

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16	16-3240/02	Condyle Cap Femur	size 2	47815 Orthopaedic implant aiming/ guiding block	11-927 Guide	1.4404	I
17	16-3240/03		size 3				
18	16-3240/04		size 4				
19	16-3213/02	Drill Cap Femur Ø 20 mm	size 2	47815 Orthopaedic implant aiming/ guiding block	11-927 Guide	1.4542	I
20	16-3213/03		size 3				
21	16-3213/04		size 4				
22	317-802/32	Chisel for patella glide 80 mm		10825 Orthopaedic chisel	10-829 Orthopaedic chisel	1.4542	I

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Container complete – Tibia							
No	Item no.	Description	Size	GMDN Code	UMDNS Code	Material	Class. EU acc. to 93/42/EEC
	15-8780/01	Container, complete, Tibia		Consisting of:			
	05-2002/03	N11 Standard container, empty		13730 Sterilization container	13-730 Sterilization container	1.4301 Al 99,5	I
	15-8781/01	Tray					
1	15-8781/01	Tray,empty		13730 Sterilization container	13-730 Sterilization container	1.4301 Al 99,5	I
2	317-802/52	Stylus for tibial saw guide (2 parts)		47815 Orthopaedic implant aiming/ guiding block	13-425 Router, Bone Cutting	1.4542 1.4404	I

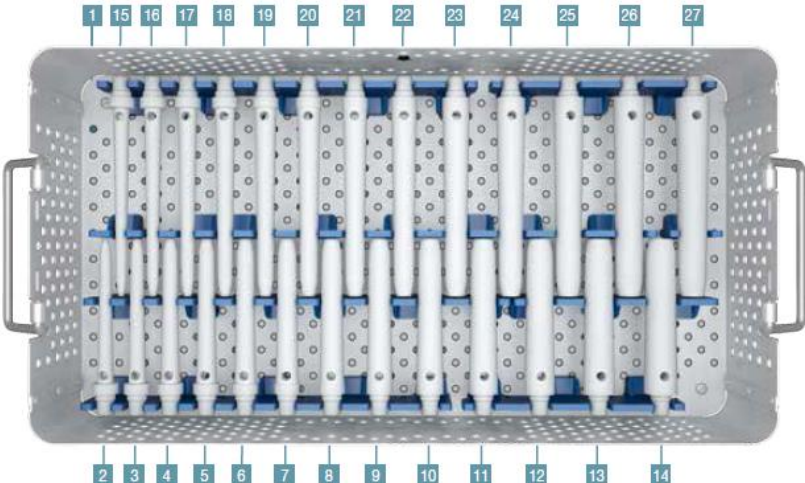
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3	16-3212/08	Connector size 8°		47847 Orthopaedic implant/ instrument adaptor, reusable	11-726 Adapter/ Connector	1.4542 1.4404	I
4	16-3197/00	Handle		47829 Surgical instrument handle	11-726 Adapter/ Connector	1.4404 1.4542	I
5	16-3207/16	Drill with stop	Ø 16 mm	32390 Surgical drill, reusable	17-995 Orthopaedic drill	1.4542	IIa
6	16-3208/18		small S Ø 18 mm,				
7	16-3208/20		medium M Ø 20 mm,				
8	16-3208/22		Large L Ø 22 mm,				
9	16-3241/00	Tibial Saw Guide		47815 Orthopaedic implant aiming/ guiding block	13-425 Router, Bone Cutting	1.4028 1.4542	I
10	16-3270/18	Drill Guide	small S Ø 18 mm,	47815 Orthopaedic implant aiming/ guiding block	11-930 Drill guide	1.4028	I
11	16-3270/20		medium M Ø 20 mm,				
12	16-3270/22		large L Ø 22 mm,				
13	16-3199/12	Compressor	small S	36167 Orthopaedic broach	13-297 Orthopaedic reamer	1.4542	I
14	16-3199/13		medium M				
15	16-3199/14		large L				

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16	16-3201/02	Stem Compressor	small S	36167 Orthopaedic broach	13-297 Orthopaedic reamer	1.4542	I
17	16-3201/03		medium M				
18	16-3201/04		large L				
19	16-3198/12	Drill Template	small S	47815 Orthopaedic implant aiming/ guiding block	11-930 Drill guide	1.4542	I
20	16-3198/13		medium M				
21	16-3198/14		large L				
22	16-3266/00	Alignment Gauge		47815 Orthopaedic implant aiming/ guiding block	11-927 Guide	1.4028	I
23	16-3267/00	Drill Guide		47815 Orthopaedic implant aiming/ guiding block	11-930 Drill guide	1.4028	I
24	16-3211/00	Guide Rod		47815 Orthopaedic implant aiming/ guiding block	11-927 Guide	1.4404	I

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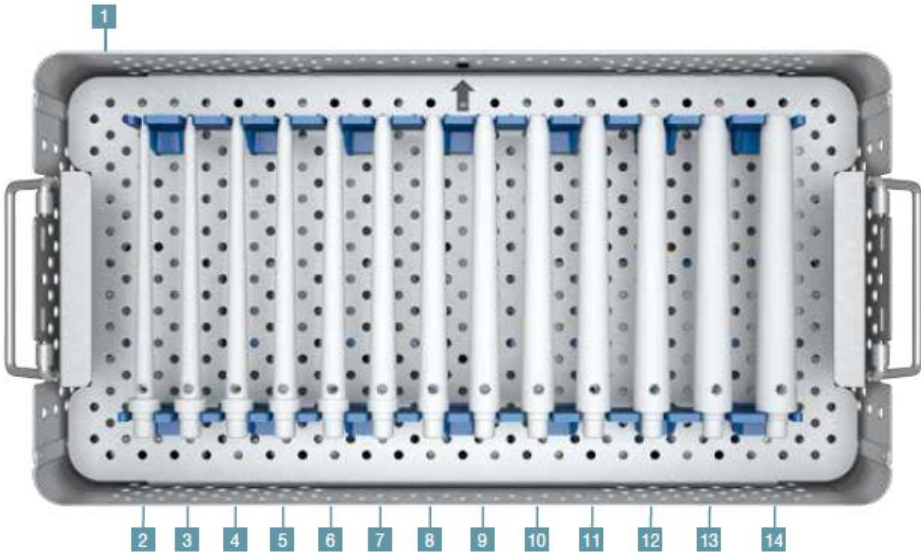
Container complete – Femur Trial Stems 100 mm and 130 mm							
No	Item no.	Description	Size	GMDN Code	UMDNS Code	Material	Class. EU acc. to 93/42/EEC
	15-8790/01	Container, complete, Femur Trial Stems 100 mm and 130 mm		Consisting of:			
	05-2001/03	N11 Standard container, empty		13730 Sterilization container	13-730 Sterilization container	1.4301, AI 99,5	I
	15-8791/01	Tray					
1	15-8791/01	Tray, empty		13730 Sterilization container	13-730 Sterilization container	1.4301, AI 99,5	I
2	16-3101/12	Trial stem 100 mm	Ø12 mm	58481 Femoral stem trial prosthesis	17-704 Trial prosthesis, Hip, Joint	PPSU	I
3	16-3101/13		Ø13 mm				
4	16-3101/14		Ø14 mm				
5	16-3101/15		Ø15 mm				
6	16-3101/16		Ø16 mm				
7	16-3101/17		Ø17 mm				
8	16-3101/18		Ø18 mm				
9	16-3101/19		Ø19 mm				

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10	16-3101/20	Trial stem 100 mm	Ø 20 mm	58481	17-704	PPSU	I
11	16-3101/21		Ø 21 mm	Femoral stem trial prosthesis	Trial prosthesis, Hip, Joint		
12	16-3101/22		Ø 22 mm				
13	16-3101/23		Ø 23 mm				
14	16-3101/24		Ø 24 mm				
15	16-3131/12	Trial stem 130 mm	Ø12 mm	58481	17-704	PPSU	I
16	16-3131/13		Ø13 mm	Femoral stem trial prosthesis	Trial prosthesis, Hip, Joint		
17	16-3131/14		Ø14 mm				
18	16-3131/15		Ø15 mm				
19	16-3131/16		Ø16 mm				
20	16-3131/17		Ø17 mm				
21	16-3131/18		Ø18 mm				
22	16-3131/19		Ø19 mm				
23	16-3131/20		Ø 20 mm				
24	16-3131/21		Ø 21 mm				
25	16-3131/22		Ø 22 mm				
26	16-3131/23		Ø 23 mm				
27	16-3131/24	Ø 24 mm					

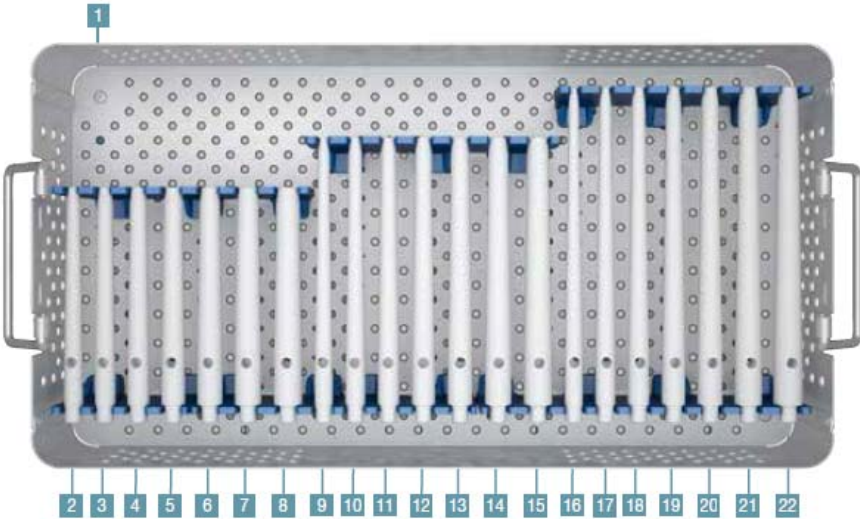
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Container complete – Femur Trial Stems 160 mm								
No	Item no.	Description	Size	GMDN Code	UMDNS Code	Material	Class. EU acc. to 93/42/EEC	
	15-8800/01	Container, complete, Femur Trial Stems 160 mm	Consisting of:					
	05-2001/03	N11 Standard container, empty		13730 Sterilization container	13-730 Sterilization container	1.4301, Al 99,5	I	
	15-8801/01	Tray 						
1	15-8801/01	Tray, empty		13730 Sterilization container	13-730 Sterilization container	1.4301, Al 99,5	I	
2	16-3161/12	Trial stem 160 mm	Ø12 mm	58481 Femoral stem trial prosthesis	17-704 Trial prosthesis, Hip, Joint	PPSU	I	
3	16-3161/13		Ø13 mm					
4	16-3161/14		Ø14 mm					
5	16-3161/15		Ø15 mm					
6	16-3161/16		Ø16 mm					
7	16-3161/17		Ø17 mm					
8	16-3161/18		Ø18 mm					
9	16-3161/19		Ø19 mm					

INSTRUMENT SET - MEGASYSTEM-C® TUMOR AND REVISION SURGERY

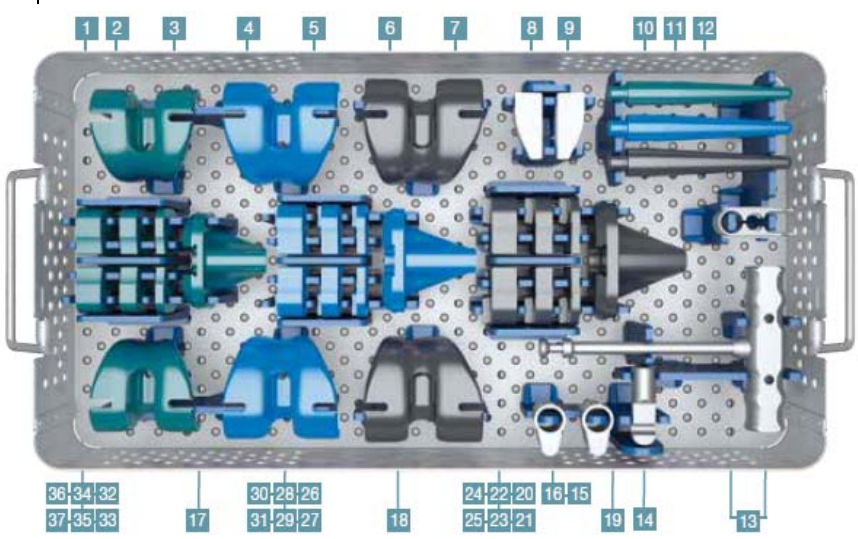
10	16-3161/20	Trial stem 160 mm	Ø 20 mm	58481	17-704	PPSU	I
11	16-3161/21		Ø 21 mm	Femoral stem trial prosthesis	Trial prosthesis, Hip, Joint		
12	16-3161/22		Ø 22 mm				
13	16-3161/23		Ø 23 mm				
14	16-3161/24		Ø 24 mm				

Container complete – Tibial Trial Stems 100, 130 and 160 mm							
No	Item no.	Description	Size	GMDN Code	UMDNS Code	Material	Class. EU acc. to 93/42/EEC
	15-8810/02	Container, complete, Tibial Trial Stems 100, 130 and 160 mm		Consisting of:			
	05-2002/03	N11 Standard container, empty		13730 Sterilization container	13-730 Sterilization container	1.4301 Al 99,5	I
	15-8811/02	Tray 					
1	15-8811/02	Tray, empty		13730 Sterilization container	13-730 Sterilization container	1.4301 Al 99,5	I

INSTRUMENT SET - MEGASYSTEM-C® TUMOR AND REVISION SURGERY

2	16-4101/12	Trial stem for modular tibia 100 mm	Ø12 mm	58716 Knee tibia trial prosthesis	13-180 Orthopaedic prosthesis implantation instrument	PPSU	I
3	16-4101/13		Ø13 mm				
4	16-4101/14		Ø14 mm				
5	16-4101/15		Ø15 mm				
6	16-4101/16		Ø16 mm				
7	16-4101/17		Ø17 mm				
8	16-4101/18		Ø18 mm				
9	16-4131/12		Trial stem for modular tibia 130 mm				
10	16-4131/13	Ø13 mm					
11	16-4131/14	Ø14 mm					
12	16-4131/15	Ø15 mm					
13	16-4131/16	Ø16 mm					
14	16-4131/17	Ø17 mm					
15	16-4131/18	Ø18 mm					
16	16-4161/12	Trial stem for modular tibia 160 mm		Ø12 mm			
17	16-4161/13		Ø13 mm				
18	16-4161/14		Ø14 mm				
19	16-4161/15		Ø15 mm				
20	16-4161/16		Ø16 mm				
21	16-4161/17		Ø17 mm				
22	16-4161/18		Ø18 mm				

INSTRUMENT SET - MEGASYSTEM-C® TUMOR AND REVISION SURGERY

Container complete – Femur and Tibial Trial Prostheses, intracondylar										
No	Item no.	Description	Size	GMDN Code	UMDNS Code	Material	Class. EU acc. to 93/42/EEC			
	15-8820/02	Container, complete, Femur and Tibial Trial Prostheses, intracondylar		Consisting of:						
	15-8811/02	Tray								
1	15-8811/02	Tray, empty		13730	13-730	1.4301	I			
2	16-3181/12	Femur Trial Prosthesis, intracondylar	small S left	58715	16-097	PPSU	I			
3	16-3181/11		small S right							
4	16-3181/12		medium M left							
5	16-3181/11		medium M right							
6	16-3181/12		large L left							
7	16-3181/11		large L right							
									Knee femur trial prosthesis	Prostheses, Joint, Knee, Femoral Component

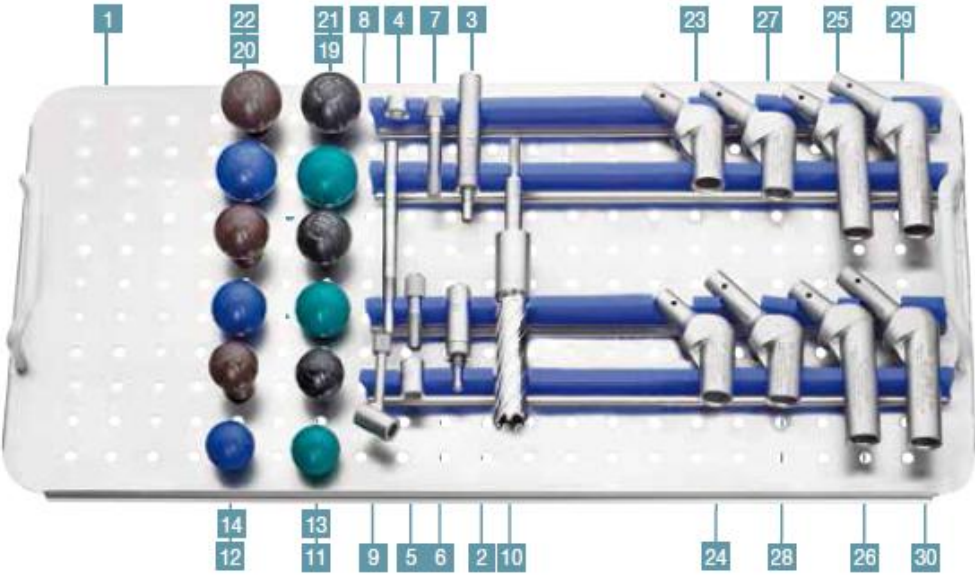
INSTRUMENT SET - MEGASYSTEM-C[®] TUMOR AND REVISION SURGERY

8	16-4368/01	Femur Trial Segment, right		58715	16-097	PPSU	I
9	16-4368/02	Femur Trial Segment, left		Knee femur trial prosthesis	Prostheses, Joint, Knee, Femoral Component		
10	16-3170/12	Tibial Trial Stems	small S	58716	16-098	PPSU	I
11	16-3170/13		medium M				
12	16-3170/14		large L				
13	15-6061/00	Extraction Instrument		12696	13-180	1.4305 1.4021	I
14	16-4367/20	Trial Axis		58716	16-098	1.4021	I
15	16-4367/00	Trial Connection Component		Knee tibial trial prosthesis	Prostheses, Joint, Knee, Tibial Component		
16	16-4367/10						
17	16-3175/12	Tibial Trial Prosthesis, intracondylar	small S	58716	16-098	PPSU	I
18	16-3175/13		medium M				
19	16-3175/14		large L				
20	16-4361/01	Tibial Trial Spacer, intracondylar, small S	5 mm, right	58716	16-098	PPSU	I
21	16-4362/01		5 mm, left				
22	16-4363/01		10 mm, right				
23	16-4364/01		10 mm, left				
24	16-4365/01		15 mm, right				
25	16-4366/01		15 mm, left				

INSTRUMENT SET - MEGASYSTEM-C® TUMOR AND REVISION SURGERY

26	16-4361/02	Tibial Trial Spacer, intracondylar, medium M	5 mm, right	58716 Knee tibial trial prosthesis	16-098 Prostheses, Joint, Knee, Tibial Component	PPSU	I
27	16-4362/02		5 mm, left				
28	16-4363/02		10 mm, right				
29	16-4364/02		10 mm, left				
30	16-4365/02		15 mm, right				
31	16-4366/02		15 mm, left				
32	16-4361/03		Tibial Trial Spacer, intracondylar, large L				
33	16-4362/03	5 mm, left					
34	16-4363/03	10 mm, right					
35	16-4364/03	10 mm, left					
36	16-4365/03	15 mm, right					
37	16-4366/03	15 mm, left					

INSTRUMENT SET - MEGASYSTEM-C® TUMOR AND REVISION SURGERY

Container L complete – Trial Prostheses Proximal Femur								
No	Item no.	Description	Size	GMDN Code	UMDNS Code	Material	Class. EU acc. to 93/42/EEC	
	15-8820/01	Container, complete, Trial Prostheses Proximal Femur	Consisting of:					
	05-2001/03	N11 Standard container, empty		13730 Sterilization container	13-730 Sterilization container	1.4301 Al 99,5	I	
	15-8821/01	Tray						
1	15-8821/01	Tray,empty		13730 Sterilization container	13-730 Sterilization container	1.4301 Al 99,5	I	
2	13-383	Drill Guide with stop	60 mm	35095	11-927	Ti6Al4V	I	
3	131-383/90		90 mm	Surgical drill guide, reusable	Guide	1.4305		
4	13-398/10	Trial Proximal Spacer	10 mm	58481	17-704	CoCrMo	I	
5	13-398/20		20 mm	Femoral stem trial prosthesis	Trial prosthesis, Hip, Joint			

INSTRUMENT SET - MEGASYSTEM-C® TUMOR AND REVISION SURGERY

6	131-397/38	Trial Fixation Screw	38 mm	58481	17-704	1.4305	I
7	131-397/58		58 mm	Femoral stem trial prosthesis	Trial prosthesis, Hip, Joint		
8	131-377/01	Guide Rod, 120 mm		13180	11-927	1.4305	I
9	131-376	Go/no Go Guide, 60 mm		Orthopaedic prosthesis implantation instrument	Guide		
10	131-384/01	Tubular Reamer 175 mm		45115 Medullary canal orthopaedic reamer, rigid	17-995 Orthopaedic drill	1.4021	Ila
11	131-928/01	Plastic trial heads Ø 28 mm	Short green	58479 Femoral head trial prosthesis	17-704 Trial prosthesis, Hip, Joint	PP-H	I
12	131-928/02		medium blue				
13	131-928/03		long black				
14	131-928/04		Extra long brown				
15	131-932/01	Plastic trial heads Ø 32 mm	Short green	58479 Femoral head trial prosthesis	17-704 Trial prosthesis, Hip, Joint	PP-H	I
16	131-932/02		medium blue				
17	131-932/03		long black				
18	131-932/04		Extra long brown				
19	131-936/01	Plastic trial heads Ø 36 mm	Short green	58479 Femoral head trial prosthesis	17-704 Trial prosthesis, Hip, Joint	PP-H	I
20	131-936/02		medium blue				
21	131-936/03		long black				
22	131-936/04		Extra long brown				

INSTRUMENT SET - MEGASYSTEM-C® TUMOR AND REVISION SURGERY

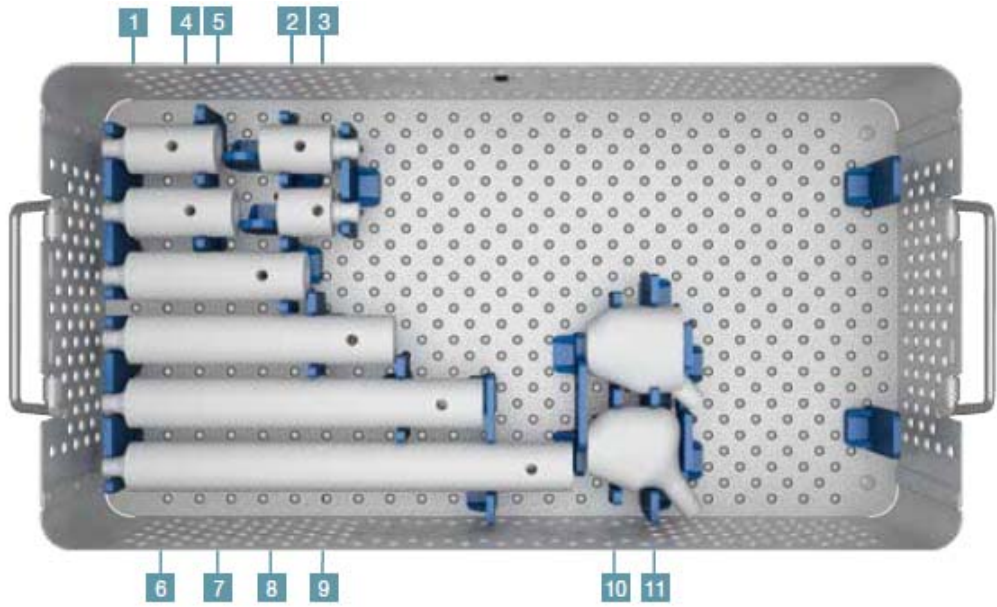
23	131-395/26	Trial neck segments	35 mm 126° CCD	58481 Femoral stem trial prosthesis	17-704 Trial prosthesis, Hip, Joint	1.4305	I
24	131-395/35		35 mm 135° CCD				
25	131-396/26		65 mm 126° CCD				
26	131-396/35		65 mm 135° CCD				
27	131-393/26	Trial neck segments XXL	35 mm 126° CCD				
28	131-393/35		35 mm 135° CCD				
29	131-394/26		65 mm 126° CCD				
30	131-394/35		65 mm 135° CCD				

INSTRUMENT SET - MEGASYSTEM-C® TUMOR AND REVISION SURGERY

Container complete – Trial Instruments for Total Femur Replacement

No	Item no.	Description	Size	GMDN Code	UMDNS Code	Material	Class. EU acc. to 93/42/EEC
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	15-8830/02	Container, complete, Trial Instruments for Total Femur Replacement		Consisting of:			
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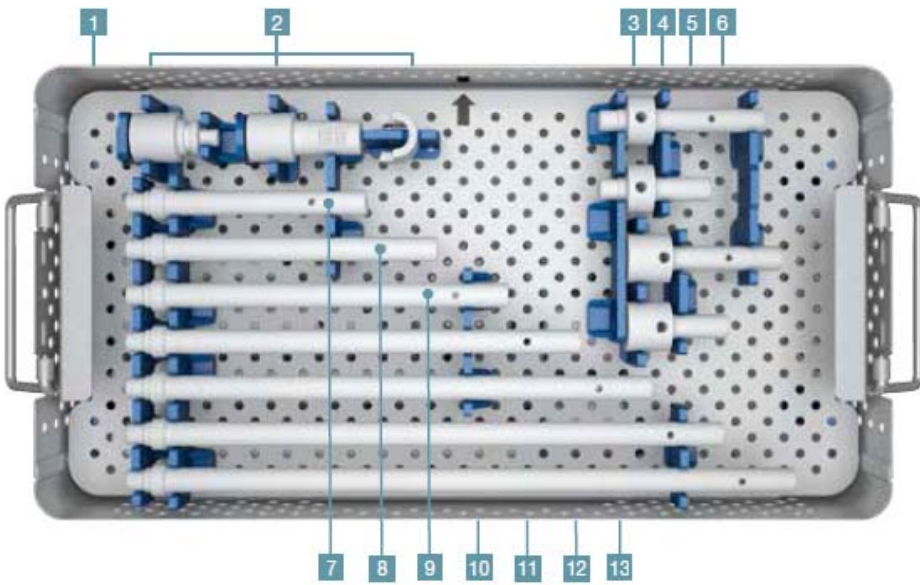
	15-8831/02	<p>Tray</p> 					
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1	15-8831/02	Tray, empty		13730 Sterilization container	13-730 Sterilization container	1.4301 Al 99,5	I
2	16-3030/01	Trial Prosthesis, for stem segments	30 mm	58715 Knee femur trial prosthesis	16-097 Prostheses, Joint, Knee, Femoral Component	PPSU	I
3	16-3040/01		40 mm				
4	16-3050/01		50 mm				
5	16-3060/01		60 mm				
6	16-3100/01		100 mm				
7	16-3150/01		150 mm				
8	16-3200/01		200 mm				
9	16-3250/01		250 mm				

INSTRUMENT SET - MEGASYSTEM-C® TUMOR AND REVISION SURGERY

10	16-3213/35	Trial Neck Segments	135°	58481	17-704	PPSU 1.4305	I
11	16-3213/26		126°	Femoral stem trial prosthesis	Trial Prostheses, Joint, Hip		

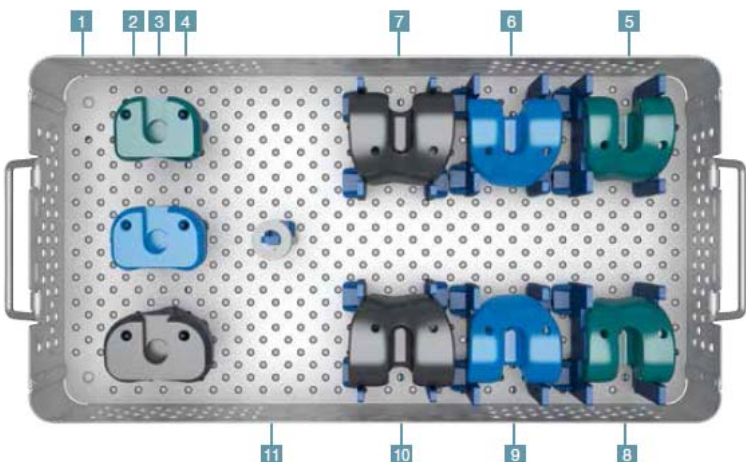
Container complete – Trial Instruments for Total Femur Replacement

No	Item no.	Description	Size	GMDN Code	UMDNS Code	Material	Class. EU acc. to 93/42/EEC
	15-8830/02	Container, complete, Trial Instruments for Total Femur Replacement		Consisting of:			
	15-8831/02	Tray 					
1	15-8831/02	Tray, empty		13730 Sterilization container	13-730 Sterilization container	1.4301 Al 99,5	I
2	16-3204/01	Trial Prosthesis (3 parts)		58715 Knee femur trial prosthesis	16-097 Prostheses, Joint, Knee, Femoral Component	PPSU	I

INSTRUMENT SET - MEGASYSTEM-C® TUMOR AND REVISION SURGERY

3	16-3212/26	Coupling, for Total Femur Replacement	long	58481 Femoral stem trial prosthesis	17-704 Trial prosthesis, Hip, Joint	PPSU	I				
4	16-3212/24		short								
5	16-3212/30	Coupling, for Proximal Femur Replacement	long								
6	16-3212/28		short								
7	16-4120/01	Trial Prosthesis for push-through stems	120 mm					58715 Knee femur trial prosthesis	16-097 Prostheses, Joint, Knee, Femoral Component	1.4305	I
8	16-4160/01		160 mm								
9	16-4200/01		200 mm								
10	16-4240/01		240 mm								
11	16-4280/01		280 mm								
12	16-4320/01		320 mm								
13	16-4360/01		360 mm								

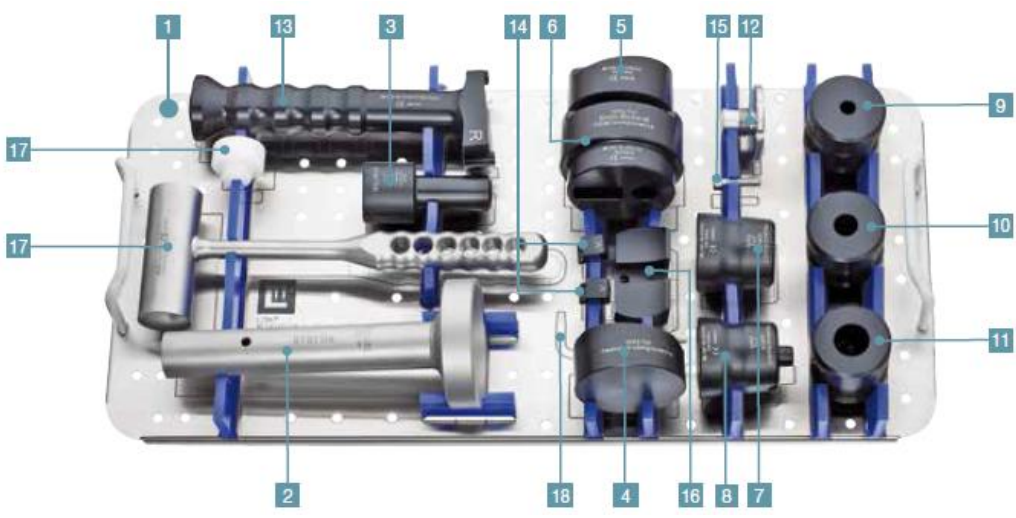
INSTRUMENT SET - MEGASYSTEM-C® TUMOR AND REVISION SURGERY

Container complete – Trial Instruments for Distal Femur and Proximal Tibia Replacement							
No	Item no.	Description	Size	GMDN Code	UMDNS Code	Material	Class. EU acc. to 93/42/EEC
	15-8840/01	Container M, complete, Trial Instruments for Distal Femur and Proximal Tibia Replacement		Consisting of:			
	15-8831/01	Tray					
1	15-8841/01	Tray,empty		13730 Sterilization container	13-730 Sterilization container	1.4301 Al 99,5	I
2	16-3180/12	Trial Prosthesis for proximal tibial replacement	small S	58716 Knee tibia trial prosthesis	16-098 Prostheses, Joint, Knee, Tibial Component	PPSU	I
3	16-3180/13		medium M				
4	16-3180/14		large L				
5	16-3191/12	Trial Prosthesis for distal femur replacement	small S, left	58715 Knee femur trial prosthesis	16-097 Prostheses, Joint, Knee, Femoral Component	PPSU 1.4404	I
6	16-3193/12		medium M, left				
7	16-3195/12		large L, left				

INSTRUMENT SET - MEGASYSTEM-C® TUMOR AND REVISION SURGERY

8	16-3191/11	Trial Prosthesis for distal femur replacement	small S, right	58715 Knee femur trial prosthesis	16-097 Prostheses, Joint, Knee, Femoral Component	PPSU 1.4404	I
9	16-3193/11		medium M, right				
10	16-3195/11		large L, right				
11	15-6094/00	Trial Support Ring, Ø 28 mm, Height 10 mm		58715 Knee femur trial prosthesis	13-180	PPSU	I

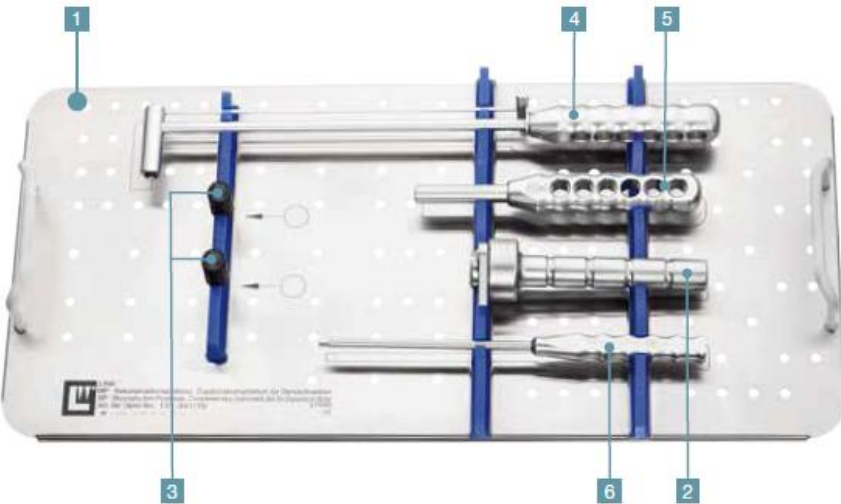
INSTRUMENT SET - MEGASYSTEM-C® TUMOR AND REVISION SURGERY

Container complete – Assembling Instrument Set							
No	Item no.	Description	Size	GMDN Code	UMDNS Code	Material	Class. EU acc. to 93/42/EEC
	16-0100/00	Container O, complete, Assembling Instrument Set		Consisting of:			
	05-2002/03	N11 Standard container, empty		13730 Sterilization container	13-730 Sterilization container	1.4301 Al 99,5	I
	16-0100/01	Tray					
1	16-0100/01	Tray,empty		13730 Sterilization container	13-730 Sterilization container	1.4301 Al 99,5	I
2	16-0118/01	Assembling table: upper part		13180 Orthopaedic prosthesis implantation instrument	13-949 Table	1.4305	I
3	16-0118/03	Assembling table: silencer					
4	16-0110/01	Femur assembling plate					
5	16-0110/02	Tibia assembling plate (SL)					
6	16-0110/03	Tibia assembling plate					

INSTRUMENT SET - MEGASYSTEM-C® TUMOR AND REVISION SURGERY

7	16-0111/01	Assembling protector for femal taper		34004 Guard, instrument	13-563 Guard	PP-H	I	
8	16-0111/02	Assembling protector for male taper						
9	16-0112/01	Assembling protector	size 1					
10	16-0112/02		size 2					
11	16-0112/03		size 3					
12	16-0113/01	Metal core						1.4305
13	16-0114/01	Handle						PP-H
14	16-0114/02	Block						PP-H
15	16-0114/04	Screw						1.4301
16	16-0114/03	Plate						PP-H
17	16-0115/01	Mallet 800g		32312 Hammer, surgical	12-421 Hammer	1.4305 1.4301	I	
18	16-0116/02	Hex Screwdriver, hex 5 mm		33968 Surgical screwdriver, reusable	13-517 Screwdriver	1.4021	I	

INSTRUMENT SET - MEGASYSTEM-C® TUMOR AND REVISION SURGERY

Container P complete – Complementary Instrument Set for Expansion Bolts							
No	Item no.	Description	Size	GMDN Code	UMDNS Code	Material	Class. EU acc. to 93/42/EEC
	131-340/04	Container P, Complementary Instrument Set for Expansion Bolts		Consisting of:			
	05-2001/03	N11 Standard container, empty		13730 Sterilization container	13-730 Sterilization container	1.4301 Al 99,5	I
	131-341/10	Tray 					
1	131-341/10	Tray, empty		13730 Sterilization container	13-730 Sterilization container	1.4301 Al 99,5	I
2	131-378/10	Holder 150 mm		13180 Orthopaedic prosthesis implantation instrument	13-180 Orthopaedic prosthesis implantation instrument	1.4112 1.4305	I
3	131-378/11	Plastic sleeves		47831 Surgical instrument sleeve, reusable	13-180 Orthopaedic prosthesis implantation instrument	PP-H	I

INSTRUMENT SET - MEGASYSTEM-C® TUMOR AND REVISION SURGERY

4	131-385/10	Torque wrench 380 mm, key width 8 mm	47858 Surgical instrument torque limiter	13-180 Orthopaedic prosthesis implantation instrument	1.4305 1.4021	I
5	131-385/01	Screwdriver 185 mm , key width 8 mm	33968 Surgical screwdriver, reusable	13-517 Screwdriver	1.4305 1.4021	I
6	131-378/20	Hex wrench 244 mm, key width 5 mm	32871 Wrench, surgical	13-180 Orthopaedic prosthesis implantation instrument	1.4305 1.4021	I

INSTRUMENT SET - MEGASYSTEM-C® TUMOR AND REVISION SURGERY

Accessories					
Item no.	Description	GMDN Code	UMDNS Code	Material	Class. EU acc. to 93/42/EEC
15-8516/61	X-ray Templates for LINK® MEGASYSTEM-C® with SL® knee components				
317-661	Guide Rod with Slaphammer	32312 Hammer, surgical	12-421 Hammer	1.4305	I

6 Labeling

The following section provides an overview of the existing catalogs and gives examples for direct and indirect labeling of the instrument set.

6.1 Direct labeling

According to DIN EN ISO 16061 the instruments are marked with the companies name and logo, item number, lot or serial number and size. Devices are not marked in the functional area, which could have impact on the intended function or reprocessing.

6.2 Indirect labeling





According to DIN EN ISO 16061 all device packagings shall be labeled. The labeling includes the necessary information. The labels are printed in English and German language. Additional languages are available.

INSTRUMENT SET - MEGASYSTEM-C® TUMOR AND REVISION SURGERY

6.2.1 Sample Label



6.2.2 Abbreviations/ Symbols

Qty.	Number of units in the package
	Observe the enclosed instructions for use
	Article number
	Serial number
	Batch number

6.3 Catalog

Catalog	Print no.	Language
Catalog: MEGASYSTEM-C® Tumor and Revision Surgery	LINK 909_Mega-C_Impl.Inst_en_2016-09_001_Z1	English

7 Packaging

Link Instrument sets are packed unsterile on storage trays in stackable sterilizing containers which ensure product integrity during shipping and storage. The used packaging materials are suitable for contact with medical instruments. They are at least approved for food contact.