Instructions for use tray systems

WIMEDICAL GMBH

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1 Symbols used

Symbol	Definition of
	CE labelling
	Attention
	Manufacturer

2 Introduction

When you purchase a WiMedical tray system, you are acquiring a high-quality product that requires correct handling and reprocessing to maintain its value. We would like to point out that the proper use of the product is of crucial importance in order to minimise potential risks and exposure for patients, users and third parties. For this reason, we strongly recommend that you read the instructions for use carefully and keep them in a safe place. Please observe the national regulations of your country. Please note that, in accordance with the MPBetreibV, proper reprocessing as per paragraph 1 sentence 2 is presumed if the joint recommendation of the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute and the Federal Institute for Drugs and Medical Devices on the hygiene requirements for the reprocessing of medical devices is observed.

In accordance with paragraph 1 of this article, the reprocessing of medical devices intended for use in a low-germ or sterile state must be carried out using appropriate validated procedures, taking into account the manufacturer's instructions, in such a way that the success of these procedures is reproducibly ensured and the safety and health of patients, users or third parties is not jeopardised. This also applies to medical devices that are disinfected or sterilised before being used for the first time

We are aware that the correct use of the WiMedical tray system is of great importance for successful use in your practice or clinic. We have therefore written the instructions for use in detail and precisely to ensure that you can make optimum use of the product. Thank you for your confidence in our product. We wish you every success in using the WiMedical tray system

Yours sincerely

The WiMedical team

3 Scope of validity

The WiMedical tray systems consist of the Munditia System Case family with the Munditia System Case Flex Smart, the Munditia System Case Flex Hybrid, the Munditia System Case Standard, the Munditia System Case Special and the Munditia System Case Customised. These are developed and manufactured according to customer requirements. Hereafter referred to as tray systems. The models consist of a case and can optionally have a lid and inlays. This applies to all models with or without flexible or integrated holders in the base and lid. Metal, silicone and plastic holders are also available. With the Munditia System Case Hybrid, the colour of the silicone corners can be selected according to the RAL colour chart. It is possible to integrate rinsing adapters. The perforations range from 0.5 x 0.5 mm to 50 x 50 mm. The tray sizes range from 20 x 20 x 20 mm to 2000 x 2000 x 2000 mm. The tray systems enable the safe storage, rinsing and sterilisation of medical instruments (scissors, clamps, forceps, hammers, nails, endoscopes, endoscopic instruments, implant and screw systems, standard medical instruments) and textiles.

WiMedical article numbers				
DS-242510	LLVKW-002	R66-T056XX-PH-1	10002	10275
DS-24253	LLW-001	R66-T076XX-01-NXG-3	10018	10276
DS-24255	LLW-002	R66-T106XX-IM-1	10020	10277
DS-24257	LLW-003	R66-T106XX-PH-2	10021	10278
DS-402510	LLW-004	R67-T056IN-01	10022	10279
DS-40253	LLW-005	R67-T106XX-01	10023	10280
DS-40255	SIS-3525	SS-01-10	10024	10281
DS-40257	SIS-5825	XH-10244-001	10025	10282
DS-482510	SPL-10	XH-10244-001-1	10026	10283
DS-48253	SPL-2	XH-10244-001-2	10028	10284
DS-4825450	SPL-4	XH-10244-002	10029	10285
DS-4825460LB	SPL-6	10028-001-1	10030	10286
DS-48255	SPL-H1-UNI-1	10028-001-2	10066	10287
DS-48257	VS-001	10067-01-1	10067	10288
DS-512510	VS-002	10067-01-2	10068	10289
DS-51255	VS-003	10067-01-3	10069	10290
DS-51257	VSN-003	10067-01-4	10070	10291
DSS-5115	889417	10248-01-01	10071	10292
KSK-001	SK-105	10248-01-02	10072	10293
KSK-002	SK-106	10248-01-02-1	10073	10294
KSK-003	SK-107	10248-01-02-10	10074	10295
KSK-004	SK-108	10248-01-02-12	10075	10296
KSK-005	SK-109	10248-01-02-2	10076	10297
WiMedical article numbers				

M11004-4	SK-110	10248-01-02-3	10078	10298
M70030050	SK-111	10248-01-02-4	10079	10299
100000-0	SK-112	10248-01-02-5	10080	10300
100002-1	10028-001	10248-01-03	10081	10301
100004-1	10028-002-1	10248-01-03-1	10082	10302
100006-1	10028-002-2	10248-01-03-2	10083	10303
100008-1	10028-002-3	10248-01-03-3	10084	10304
11-11008-FE	10028-002-4	10248-01-03-4	10085	10305
11000-0	10067-01	10248-01-03-5	10086	10306
11000-0-FE	10088-001	10248-02-02-1	10087	10307
11002-1	10088-002	10248-02-02-2	10088	10308
11004-1	10088-003	10248-02-02-3	10089	10309
11006-1	10088-004	10248-02-02-4	10090	10310
11008-1	10088-005	10248-02-02-5	10091	10311
12000-0	10088-006	10248-02-03-1	10092	10312
12002-1	10088-007	10248-02-03-2	10093	10313
12004-1	10088-008	10248-02-03-3	10094	10314
12006-1	10088-009	10248-02-03-4	10095	10315
12008-1	10088-010	10248-02-03-5	10096	10316
34000-0	10088-011	10248-03-2	10097	10317
34000-8	10088-012	10248-03-3	10098	10318
34002-1	10088-013	10248-04-02-2	10099	10319
34004-1	10088-014	10248-04-02-3	10100	10320
34004-8	10088-015	10248-04-02-4	10101	10321
34006-1	10088-016	10248-04-02-5	10102	10322
34008-1	10088-017	10248-04-02-6	10103	10323
BIG PACK 100	10088-018	10248-04-2	10104	10324
BIG PACK 11	10088-019	10253-001-1	10105	10325
BIG PACK 12	10088-020	10253-001-2	10106	10326
BIG PACK 34	10088-022	10253-001-3	10107	10327
AH-10-1	10088-023	54-540-00-01	10108	10328
AH-20-1	10125-002	54-540-00-2-S	10109	10329
AH-30-1	10126-34-34000	54-540-00-U-1	10110	10330
AH-40-1	10152-000	54-540-00-U-2	10111	10331
AH-60-1	10152-001	54-540-00-U-3	10112	10332
FH-26-1	10152-002	54-540-00-U-4	10113	10333
FH-36-1	10200-0	54-540-00-U-5	10114	10334
FH-46-1	10200-1	54-540-10-02	10115	10335
WiMedical article numbers				

FH-66-1	10200-3	54-540-10-03	10116	10336
FH-86-1	10201-010	54-540-10-04	10117	10337
Lap set 1.1	10203-001	54-540-10-05	10118	10338
Lap set 1.2	10209-001	54-540-10-2	10119	10339
Lap set F1	10209-002	54-540-10-3	10120	10340
SS-04	10209-003	54-540-10-S	10121	10341
SS-08	10209-004	54-540-20-02	10122	10342
SS-248	10209-005	54-540-20-03	10123	10343
SS-476	10209-006	54-540-20-04	10124	10344
49999	10209-20	54-540-20-05	10125	10345
50000	10211-001	54-540-20-2	10126	10346
50001	10211-002	54-540-20-3	10127	10347
50002	10211-003	54-540-20-4	10128	10348
50003	10211-004	54-540-20-5	10129	10349
50004	10211-005	54-540-20-S	10130	10350
50005	10211-006	54-540-50 NIR-01	10131	10351
50006	10211-007	54-540-50 NIR-02	10132	10352
50007	10211-008	54-540-50 NIR-04	10133	10353
50008	10213-A6601.034	54-540-50 NIR-05	10134	10354
50009	10213-A6602.002	54-540-50 NIR-06	10135	10355
50010	10213-M-6721X	54-540-50-NIR-S	10136	10356
50011	10216-34-34004-1	EH-001-1	10137	10357
50012	10221-001	L-537240106-B	10138	10358
50013	10221-002	L-53724056-B	10139	10359
50014	10221-003	L-540243-D	10140	10360
50015	10221-005	R66-T05613-Z1 TRAY-1	10141	10361
60000	10221-005-5	R66-T05613-Z1 TRAY-2	10142	10362
60001	10230-001	R66-T05613-Z1 TRAY-3	10143	10363
60002	10230-002	R66-T05613-Z1 TRAY-4	10144	10364
60003	10236-001	R66-T05613-Z1 TRAY-5	10145	10365
60004	10236-002	R66-T05613-Z1 TRAY-6	10146	10366
60005	10236-003-1	R66-T05613-Z1 TRAY-7	10147	10367
60006	10236-003-2	R66-T05613-Z1 TRAY-8	10148	10368
60007	10236-004	R66-T05613-Z1 TRAY-9	10149	10369
60008	10236-005	R66-T05613-Z1-1	10150	10370
60009	10236-006	R66-T05613-Z1-LID2	10151	10371
60010	10247-001	R66-T05613-Z1-TRAY2	10152	10372

WiMedical article numbers				
60011	10247-001-01	R66-T05613-Z1TRAY-10	10153	10373
60011-10	10247-001-02	R66-T05613-Z1TRAY-14	10154	10374
60012	10247-001-03	RO-11-11008-01	10155	10375
60013	10248-01	RO-11-11008-02	10156	10376
60014	10248-01-015	RO-11-11008-03	10157	10377
60015	10248-01-04	RO-11-11008-04	10158	10378
60016	10248-02	RO-11-11008-05	10159	10379
60017	10248-02-02	01-10000	10160	10380
60020	10248-03	01-10001	10161	10381
60021	10248-03-01	D1000	10162	10382
60022	10248-04	D1001	10163	10383
60050	10248-04-01	D1003	10164	10384
69999-10	10248-05	D1004	10165	10385
889626	10248-05-01	D1005	10166	10386
890010	10248-06	D1006	10167	10387
890011	10248-06-01	D1007	10168	10388
9200-S	10250-002	D1008	10169	10389
990076	10250-002-1-1	DB2001	10170	10390
SM-540320	10250-002-2-1	DB2002	10171	10391
SM-541240	10250-002-2-2	DB2003	10172	10392
SS-01	10250-002-2-3	DB2004	10173	10393
SS-02	10250-002-2-4	EN9001-10105-001	10174	10394
SS-03	10250-002-2-5	DOP-1-11007	10175	10395
SS-04-10	10250-002-2-6	DOP-1-11008	10176	10396
10-10000	10250-002-6	DSP-001	10177	10397
10-100002-1	10252-000	GC-Special 1	10178	10398
10-100004-1	10252-001	GC Special 2	10179	10399
10-100006-1	10253-001	HAG-S-90019 REV1	10180	10400
10-100008-1	10255-001	HAG-S-90019SLRev1	10181	10401
10-100010-1	10255-002	HD11001	10182	10402
10-100010-2	10255-003	HD11002	10183	10403
10125-001	10255-004	HD11003	10184	10404
11-11000	10255-005	HD11004	10185	10405
11-11000-1-8E	10259-001	HD11005	10186	10406
11-11002-1	10259-002	HD11006	10187	10407
11-11002-1-6E	10259-003	HD11007	10188	10408
11-11004-1	10259-004	HD11008	10189	10409

WiMedical article numbers				
11-11004-1-6E	10260-001	HD12001	10190	10410
11-11006-1	10261-004	HD12002	10191	10411
11-11006-1-6E	10261-005	HD12003	10192	10412
11-11008-1	10261-01	HD12004	10193	10413
11-11008-1-8E	10261-02	HD12005	10194	10414
11-11010-1	10261-03	HD12006	10195	10415
11-11010-2	10261-04	HD12007	10196	10416
11-11010-2-8E	10261-05	HD12008	10197	10417
11-11010-3	10261-06	HD12009	10198	10418
11-Sample article	10261-07	HD34001	10199	10419
12-12000	10261-08	HD34002	10200	10420
12-12002-1	10261-09	HD34003	10201	10421
12-12004-1	10261-10	HD34004	10202	10422
12-12006-1	10262-001	HD34005	10203	10423
12-12008-1	10262-002	HD34006	10204	10424
12-12010-1	10262-002-S	HD34007	10205	10425
12-12010-2	10262-003	HD34008	10206	10426
12-Sample article	10262-003-S	ORS-1-12005	10207	10427
34-34000	10262-004	ORS-1-12005BRev1	10208	10428
34-34002-1	10262-004-1	ORS-1-12005DRev1	10209	10429
34-34004-1	10262-005	ORS-1-12005TBRev1	10210	10430
34-34006-1	10262-005-1	OS-3001	10211	10431
34-34008-1	10262-005-2	RU-12003	10212	10432
34-34010-1	10262-005-3	S-9200	10213	10433
34-34010-2	10262-005-4	S-9201	10214	10434
889551	10270-000	S-9202	10215	10435
EH-001	10270-001	S-9203	10216	10436
EH-002	10270-001-1	S-HD11008	10217	10437
GYN-11014-1	10270-002	S-Q-S005 Screw Caddy	10218	10438
HS-70030050	10270-002-01	Si bar 5x5	10219	10439
KS-001	10270-002-02	X-8003	10220	10440
LAP-11012-1	10270-003	X-8005	10221	10441
RO-11-11000	10271-001	X-8005-1	10222	10442
RO-11-11008	10271-002	100000	10223	10443
SL-100	10271-003	100011	10224	10444
SL-50	10273-001	990275	10225	10445
URO-001	10278-001	990278	10226	10446
URO-11013-1	10283-001	990294	10227	10447

WiMedical article numbers				
XL-540x243x66	10283-001-1	EZ 1.4108	10228	10448
XXL-3-582252-E-6E	10283-001-2	LZ 1.4108	10229	10449
XXL-580252117-B-6E	10283-001-3	TR50G5	10230	10450
XXL-580252170-B-6E	10283-001-4	100003	10231	10451
XXL-582252-E-6E	11-11000-1-1-6E	100005	10232	10452
990010	11-11004-12	100007	10233	10453
990320	54-540-00	11001	10234	10454
KE-106-1	54-540-00-2	11003	10235	10455
KE-106-10	54-540-00-O-1	11005	10236	10456
KE-106-11	54-540-00-O-2	11007	10237	10457
KE-106-12	54-540-00-T1	12001	10238	10458
KE-106-13	54-540-00-T2	12003	10239	10459
KE-106-14	54-540-10	12005	10240	10460
KE-106-14-1	54-540-10-1	12007	10241	10461
KE-106-2	54-540-20	34001	10242	10462
KE-106-3-1	54-540-20-1	34003	10243	10463
KE-106-4	54-540-50 NIR-03	34005	10244	10464
KE-106-5	54-540-50-NIR	34007	10245	10465
KE-106-6	54-540-60	KE-36-1	10246	10466
KE-106-6-1	60015-10	KE-36-10	10247	10467
KE-56-7-1	AH-20-1-10	KE-36-11	10248	10468
KE-56-8	FH-36-1-10	KE-36-12	10249	10469
KE-56-9	R62-T05613-Z1-LID	KE-36-13	10250	10470
100002	R62-T05613-Z1-TRAY	KE-36-2	10251	10471
100004	R64-T05606-L1	KE-36-3	10252	10472
100006	R64-T05606-L1 TRAY	KE-36-4	10253	10473
100008	R64-T05606-L1 TRAY-2	KE-36-5	10254	10474
11002	R64-T05606-L1 TRAY-3	KE-36-6	10255	10475
11004	R64-T05606-L1 TRAY-4	KE-36-7	10256	10476
11006	R64-T05606-L1 TRAY-5	KE-36-8	10257	10477
11008	R64-T05606-L1 TRAY-6	KE-36-9	10258	10478
12002	R64-T05606-L1 TRAY-7	KE-76-1	10259	10479

WiMedical article numbers				
12004	R64-T05606-L1 TRAY-8	KE-76-10	10260	10480
12006	R64-T05606-L1 TRAY-9	KE-76-11	10261	10481
12008	R64-T05606-L1TRAY-10	KE-76-12	10262	10482
34002	R64-T05608-A1 TRAY	KE-76-13	10263	10483
34004	R64-T05608-A2 TRAY	KE-76-2	10264	10484
34006	R64-T05608-A3 TRAY	KE-76-3	10265	10485
34008	R64-T05608-A4	KE-76-4	10266	
DE9001	R66-T00100-01	KE-76-5	10267	
DE9002	R66-T05613-Z1	KE-76-6	10268	
DE9002-1	R66-T05613-Z1 TRAY	KE-76-7	10269	
DE9003	R66-T056XX-01-NXG-1	KE-76-8	10270	
LLM-001	R66-T056XX-01-NXG-2	KE-76-9	10271	
LLM-002	R66-T056XX-01-PST	KE-IB-001	10272	
LLM-004	R66-T056XX-IM-2		10273	
LLM-005	LLVKM-001		10274	

4 Warnings

The medical devices are supplied non-sterile and must be cleaned, disinfected and sterilised before first use.	⚠
Defective products must not be used and must have undergone the entire reconditioning process before being returned.	⚠
Please observe the additional instructions enclosed with the product!	⚠
Remove all protective covers and protective films before first use or preparation.	⚠
The safe combination of the products must be checked by the user before clinical use.	⚠

Avoid improper throwing or dropping of the products.	
To avoid any contact corrosion, products with damaged surfaces must be discarded immediately!	
If the products are used on patients with Creuzfeldt-Jakob disease or HIV infection, we decline all responsibility for reuse.	

The instruments should only be used and sterilised by professionally qualified personnel. In the event of damage, even during use, the product must be replaced immediately. Any further use may lead to complications and/or danger to persons during the procedure.

5 Area of application

The tray systems represent a reliable reprocessing solution that combines proven holding techniques, tested materials and design features. Our reusable tray systems offer a wide range of dimensions and features and, in accordance with the definition in §3 No. 14 MPG, ensure effective reprocessing, compliance with the requirements of §8 MPBetreibV, storage and aseptic presentation of the medical devices to be reprocessed.

Our tray systems are suitable for steam sterilisation processes in accordance with DIN EN 285:2021-12 and DIN EN 13060:2019-02. They are used to load medical devices that are to be reprocessed, i.e. cleaned, disinfected, packaged and, if necessary, sterilised. The tray systems can be packed in packaging in accordance with DIN EN ISO 110607. However, the manufacturer's instructions for the sterile barrier systems used must be observed.

The tray systems are used in the central sterile supply department (CSSD) or reprocessing unit for medical devices (RUMED), in functional departments such as the operating theatre and in doctors' surgeries. We are aware that effective reprocessing of medical devices is of the utmost importance and are pleased to be able to offer you a reliable solution with our tray systems.

5.1 Intended use

Tray system for the reprocessing, storage and aseptic presentation of reprocessable medical devices up to and including "Critical B" (in accordance with KRINKO/BfArM recommendation "Hygiene requirements for the reprocessing of medical devices from 01/10/2012) and textiles for surgical use in specialist surgical areas in rooms used for medical purposes. The products are intended to be prepared and used by trained medical professionals and are not intended for use by the patient themselves.

Please note that according to MPBetreibV §4, medical devices may only be operated and used in accordance with their intended purpose and in accordance with the provisions of this ordinance and the generally recognised rules of technology. "Medical devices may only be operated or used by persons who have the necessary training or knowledge and experience." [1]

"Instruction in the proper handling of the medical device is required. By way of derogation from sentence 1, instruction is not required if the medical device is self-explanatory or if instruction has already been provided for an identical medical device. Instruction in the proper handling of active non-implantable medical devices must be documented in a suitable form."[2]

5.2 Contraindications

CJD - Creutzfeldt-Jakob disease

BSE - Bovine spongiform encephalopathy; so-called mad cow disease (e.g. Creutzfeldt-Jakob disease)

TSE - Transmissible spongiform encephalopathy

The doctor in charge must decide whether the intended application can be carried out on the basis of the patient's general condition.

If Creutzfeldt-Jakob disease is suspected or diagnosed, measures must be taken to prevent possible transmission to other patients, users and third parties.

The country-specific reprocessing guidelines must be observed.

6 Preparation

Restrictions and limitations on reprocessing:

No restriction on reprocessing cycles

[1] MPBetreibV §4 paragraph 2
[2] MPBetreibV §4 paragraph 3

The end of the product's service life is normally determined by wear and damage caused by use. Defective products can be returned in decontaminated condition or scrapped. Repair is not intended. Laser-marked products can fade when treated with basic cleaners containing phosphoric acid and hydrofluoric acid. As a result, the coding function may be impaired or lost.

6.1 General

The tray systems are made of stainless steel sheet whose surface is electropolished to protect against corrosion. They also guarantee a short drying phase due to their high thermal conductivity. Aggressive cleaning agents, metal brushes or scouring pads can permanently damage this surface and must therefore not be used. Failure to follow these instructions will invalidate the guarantee. The tray system may only be handled by instructed or trained personnel in order to prevent damage to the containers and closures.

To ensure the protection of patients, users and third parties, it is necessary that the tray systems are cleaned, disinfected and sterilised before each use and transport (e.g. for repair work) in accordance with these instructions for use. Especially when using for the first time, as all products are delivered non-sterile.

As part of your responsibility for the sterility of the products during use, please always ensure that only sufficiently device and product-specific validated procedures are used for reprocessing and that the devices used, such as washer-disinfectors and sterilisers, are maintained and checked in accordance with the national specifications and manufacturer's instructions so that the validated parameters are complied with for each cycle. Please also observe the legal and hygiene regulations of the medical practice or hospital applicable in your country.

6.2 Commissioning a brand new tray

1. all products must be removed from the transport packaging before use; other packaging, protective caps and protective films etc. must be removed and disposed of in an environmentally friendly manner

When working with the Munditia System Case Flex Smart and Hybrid, the spring and shaft holders must be snapped into the desired position in the drain slots in the lid and base. Ensure that the spring holders are fitted in the lid and the wave holders in the base.

2 Before using the products for the first time, subject them to a complete reprocessing cycle as described in the previous chapter.

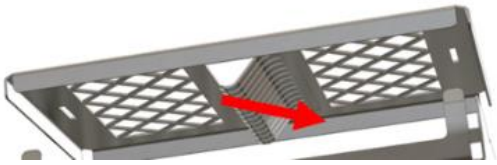
6.3 Preparation for cleaning

1. if there is a cover, open it

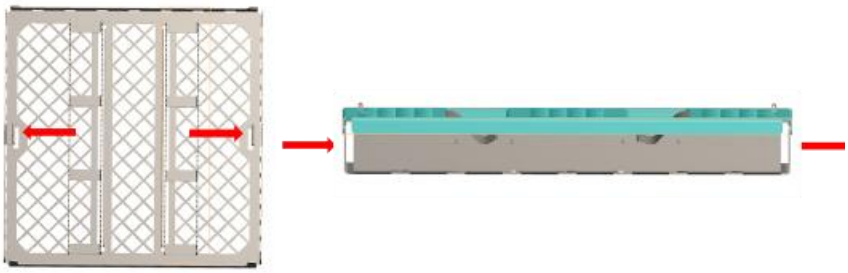
2. remove the contents of the tray

3. cleaning of instruments and medical devices according to their instructions for use

4. check the function of the holders and the tension of the spring holders, pull them back slightly if necessary so that they tension the medical device (see illustration).



5 For tray systems with a protruding opening mechanism, check whether the closing mechanism is under tension. Adjust this by pressing lightly with your thumb from the inside to the outside when the lid is open, so that the lid only engages when it is pressed lightly to the side.



6. check the tray system for damage. If the brackets are loose or damaged, contact WiMedical.

7. for tray systems with a lid, close the lid

8. pack the tray system in your usual packaging

9. carry out the sterilisation process according to the packaging manufacturer's instructions for use

6.4 Cleaning and disinfection

Note: Improper cleaning and disinfection can lead to corrosion and stress fracture. Therefore, the manufacturer's instructions for cleaning and disinfecting agents must be followed. Never clean instruments with metal brushes or steel wool. Do not oil any plastic components. Please note that the following components are not included in the cleaning agents and disinfectants: strong acids (< pH 5 / oxidising acids), alkalis (> pH 10), organic solvents, disinfectants containing alcohol, phenol, ammonia, petrol, halogens and halogenated hydrocarbons, sodium chloride in higher concentrations, oxidising agents. Only fully demineralised water (quality in accordance with DIN EN 285 Annex B) is recommended for the final rinse when reprocessing the trays.

Freshly prepared disinfectant and cleaning solutions must be used daily. The following problems can occur with prolonged use:

- Risk of corrosion due to dirt
- Risk of corrosion if concentration increases due to evaporation
- Decrease in the disinfection effect due to contamination

Please observe the current recommendations of the supervisory authorities and professional associations (e.g. DGSV e.V.) regarding the service life (time between use and reprocessing) of medical devices.

Please note that the tray lid can remain closed during cleaning and disinfection in a washer-disinfector. This does not apply to medical devices placed inside. Please observe the respective manufacturer's instructions for these medical devices.

6.4.1 Manual cleaning

As automated cleaning is preferable to manual cleaning due to its greater effectiveness and traceability, it is recommended that the medical devices described here are not cleaned manually. In accordance with DIN EN ISO 15883, no manual cleaning procedure is therefore specified.

6.4.2 Mechanical cleaning

Machine cleaning of the tray systems is required in washer-disinfectors in accordance with DIN EN ISO 15883. When machine cleaning, the specifications of the washer-disinfector and the manufacturer's instructions must be observed.

Neutral and mildly alkaline cleaning agents and disinfectants are suitable for cleaning. Please observe the national regulations on prion prophylaxis, as these may prescribe cleaning at a pH value > 10.

Only use water in accordance with the requirements of DIN EN ISO 15883 or DIN EN 285. The machine cleaning of the articles has been validated under the following minimum parameters:

Information on the validation of cleaning:

The materials and machines were used during validation:

Process step	Materials used
Pre-cleaning	Neodisher Mediclean Forte; Dr Weigert; Hamburg
Cleaning agent Automatic cleaning	Neodisher Mediclean Forte; Dr Weigert; Hamburg
Neutraliser:	Fully demineralised water

Washer-disinfector: Miele G 7836 CD

Slide-in trolley: Slide-in trolley E 327

The following minimum programme parameters were used for validation:

1. 2 min. pre-rinse with cold water
2. emptying
5. 5 min wash at 55°C +/- 5°C with 0.5 % alkaline detergent
6. emptying
7. 3 min rinse with cold demineralised water
8. emptying
9. 2 min rinse with cold demineralised water (>40°C)
10. emptying

Temperature of the cold water: 10°C - 25°C

Temperature of the cold demineralised water: 10°C - 25°C

Automated cleaning was validated with the cleaner "Neodisher Mediclean forte" in a 0.5% dosage (pH value >10). If the chemicals and machines described above are not available, it is the responsibility of the user to validate his process accordingly. It is the responsibility of the user to ensure that the reprocessing process, including resources, material and personnel, is suitable to achieve the required results. The state of the art and national laws require validated processes to be followed.

Fully demineralised water is recommended for the final rinse in accordance with the KRINKO/BfArM recommendation "Hygiene requirements for the reprocessing of medical devices" (Bundesgesundheitsbl 2012- 55:1244-1310). The washer-disinfector must be designed for cleaning trays and sieve baskets. This applies in particular to the safe positioning in the washing baskets and the arrangement of the spray nozzles or arms. The formation of spray shadows must be avoided.

The cleaning result must be checked visually. The trays and the instruments they contain must be visually clean; the process may need to be repeated. The inspection is carried out visually; critical areas such as handle structures, joints or jaw grooves require particularly careful checks.

The residues from the cleaning process must be reliably removed, as otherwise staining and/or discolouration of instruments and injuries to patients and third parties may occur. If this cannot be ruled out with certainty, a pH value measurement should be carried out after each washer-disinfector process, as this can detect any carry-over of cleaning chemicals.

6.4.3 Disinfection

The final disinfection should be carried out in compliance with the parameters required by DIN EN ISO 15883 at an A0 value of 3000 with moist heat.

Manual disinfection is not recommended due to the lack of reproducibility.

Disinfection is followed by the drying phase in compliance with the parameters required by DIN EN ISO 15883. If necessary, additional manual drying can be achieved using a lint-free cloth. Instrument cavities must be dried with medical compressed air or higher quality compressed air.

If mechanical disinfection is not possible, a fully virucidal disinfectant must be used in accordance with the manufacturer's instructions.

6.5 Inspection / functional test / care / maintenance

Carry out checks before and after each use. Do not use products that are damaged, incomplete or have loose parts.

The tray systems must be checked for functionality before each use. Damage to the fasteners, rivets, spring holders and shaft holders, as well as bent and dented parts, mean that the trays must be replaced and may no longer be used. Do not use damaged tray systems.

Only for system trays with spring holders: We recommend tightening the spring holders by hand each time a new load is placed.

Visual inspection for cleanliness and reassembly of the instruments, if necessary, repeat the reprocessing process until the instrument is visually clean.

Stained instruments are the result of inadequate reprocessing. The causes of these stains can include

- Insufficient mechanical or manual cleaning
- Unsuitable cleaning, disinfection and care products
- Non-compliance with the dosing instructions for cleaning agents, disinfectants and care products or residues (carry-over)
- Influences from the water, e.g. from foreign ions such as iron or silicate
- Residues of pharmaceuticals, marking pens or chemical indicators
- Procedural errors (e.g. failure to clean brand-new surgical instruments before sterilisation)

- Check all products after cleaning or cleaning/disinfection for loose parts, corrosion, damaged surfaces, chipping, deformation, mobility/function, hairline cracks in the joint areas, etc. and replace damaged or otherwise worn instruments.
- Corroded instruments must be removed, as they can cause corrosion on intact instruments through the transfer of extraneous rust
- Maintenance and repairs may only be carried out by WiMedical itself or by persons authorised by WiMedical to do so. This is the only way to maintain guarantees and warranty claims.
- Please only forward reprocessed products (cleaned, disinfected and sterilised) to the manufacturer.

6.6 Packaging/ Storage

We recommend carrying out sterilisation in single-use sterilisation packaging and/or sterilisation containers; these must comply with the legal requirements (e.g. DIN EN ISO/ANSI AAMI ISO 11607 / ISO 11607 / EN 868), be suitable for the sterilisation process and offer sufficient protection of the products or sterilisation packaging against mechanical damage. Please carry out regular maintenance in accordance with the manufacturer's instructions.

All sterilised products must be stored in a dry, clean, dust-free place protected from direct sunlight. The storage conditions of DIN EN ISO 11607 should be observed.

Transport and storage must not adversely affect the properties of the reprocessed medical device.

6.7 Sterilisation

Plasma hot air sterilisation is not permitted for products with plastic parts, as the plastic may be destroyed.

Recommended sterilisation procedure:

This procedure can be used for all tray sizes.

Minimum impact parameters according to DIN EN ISO 17665:

Criterion	**Description of the**
Method	3x pre-vacuum steam sterilisation
Temperature	134°C (273°F)
Holding time	3 minutes
Drying time	10 minutes
Loading	Standard medical instruments and textiles

7 Loading

The total weight of the load of the tray systems including sterile containers should not exceed the specified maximum load weight per STE slot of the steriliser used, as otherwise sufficient sterilisation cannot be guaranteed. The recommended load quantity in kilograms can be found in the instructions for use of your sterile container.

8 Placement in the steriliser

Please note that heavy containers are positioned at the bottom of the sterilisation chamber. Due to their design, containers of the same type can be stacked on top of each other during sterilisation without slipping. Stacking is only recommended for sterilisation cycles that work with high vacuum. The steriliser manufacturer's instructions must be observed.

9 Transport

Please observe the applicable standards and recommendations for the storage of medical devices.

10 Storage

Under normal clinical conditions, sterile supplies remain sterile for between a few weeks and 6 months (in unopened sterile containers and undamaged sterile filters). The storage time usually depends on the storage conditions and must be determined by the responsible hygiene specialist. In the case of particularly high asepsis requirements, it is recommended to use shorter storage periods or additional packaging.

Compliance with the storage conditions specified in DIN EN ISO 58953 Part 8 and DIN EN ISO 11607 must be ensured to prevent premature recontamination.

11 Maintenance / repair

Maintenance of the tray systems, other than the activities described in these instructions for use, may only be carried out by qualified persons and companies in accordance with § 7 MPBetreibV. Please note that the guarantee/warranty will be invalidated if WiMedical

products are serviced or repaired by maintenance companies other than those authorised by Wimedical.

12 Materials

The system trays and sieve baskets are made of stainless instrument steel.

- Housing: Material 1.4301
- Shaft holder: Material 1.4301
- Spring retainer: Material 1.4310
- Plastic: Silicone Shore 60/80FDA-CFR 21 Part.177.2600 , USP VI
- Plastic corners: Silicone Shore 80FDA-CFR 21 Part.177.2600, USP VI
- Surface finish: electropolished

The plastics used have been tested for toxicity in laboratory analyses and comply with national regulations.

13 Guarantee

The tray systems are made from high-quality materials and undergo quality control before delivery. However, should any faults occur, please contact the address below.

- WiMedical offers a 12-month guarantee on the housing, cover, shaft mounts and spring mounts.
- Gross misconduct and wilful destruction are not covered by the warranty.

wiMedical accepts NO LIABILITY IF IT IS PROVED THAT THIS USE INSTRUCTION HAS BEEN VIOLATED.

14 Returns

All returns must be machine-processed and sterilised without leaving any residue. Unsterilised products and unclean products will not be accepted. Please send our form provided for this purpose in the download area www.wimedical.de by e-mail in advance to info@wimedical.de.

Disposal: The country-specific laws and regulations must be observed for disposal.

15 Service and manufacturer address

WiMedical GmbH
Erich-Heckel-Strasse 8
D-78224 Singen
info@wimedical.de
www.wimedical.de