



21ST WORLD STERILIZATION CONGRESS

A new way for pre-cleaning surgical
medical devices using a bicarbonate
solution under pressure with a
machine Safe Clean Box STK 103-113
of Bicarjet

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CICG, GENEVA, SWITZERLAND

Why not look for a new MD pre-cleaning technology for decentralized STERs based on pressurized sodium bicarbonate?

7 WD with 18 baskets

2 large WD with 56 baskets

Operating time 6/7 days 24 hours a day, plus an extra shift on Sundays

50 employees

Turnover corresponds to approximately 120 sterile units

Long waiting time before reprocessing

→ More focus on pre-cleaning

→ High risk of corrosion

Requirement: better pre-cleaning → significant reduction in MDs to be returned for cleaning

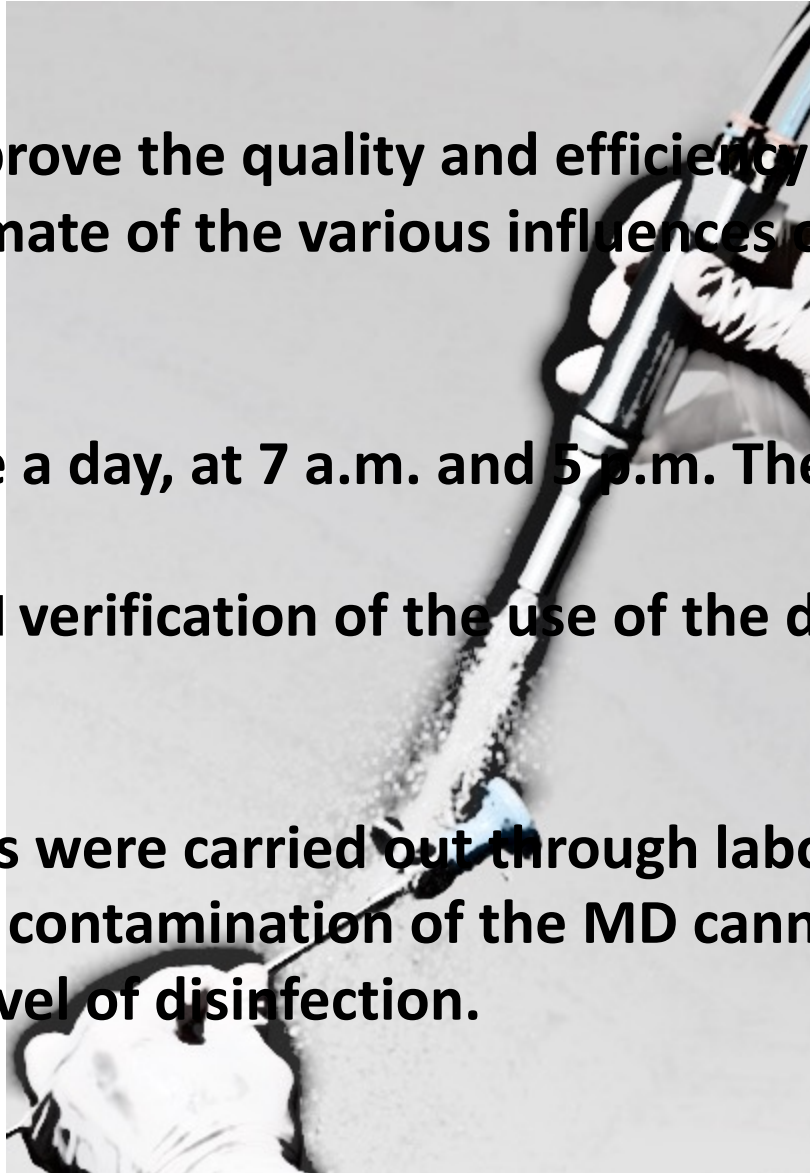
Significant drop in no of MDs to be sent for repair

The test should not only prove the quality and efficiency of the pre-cleaning process but also provide a better estimate of the various influences on our daily production and management.

We receive the MDs twice a day, at 7 a.m. and 5 p.m. The sterile MDs are returned at 2 p.m. and 5 a.m.

2 highlights in wet areas ? verification of the use of the device, without slowing down production.

Upstream, quality controls were carried out through laboratory analyzes which guarantee that additional contamination of the MD cannot take place and therefore cannot impact the final level of disinfection.



20.84,
 20 stk.

SIMICON

Qualitätszertifikat

Bio-Indikator SIMICON EF

Bio-Indikatoren zur Validierung und Routinekontrolle von
 Aufbereitungsprozessen für Endoskope nach ISO 15883-5.

Testkeim: Enterococcus faecium
 ATCC 6057

mittlere Keimzahl (KBE): $1,4 \times 10^9$
 ermittelt durch Agar-Oberflächenmethode (TSA)

Proteingehalt (μg): > 5000
 ermittelt durch OPA-Methode

Keimträger: Edelstahlplättchen V4A
 Verpackung: Papier / Folie

Organische Belastung: Schafblut und Additive

Charge: 521220

Verwendbar bis Ende: 03.2021

Bebrütung: 4 Tage bei $35^\circ\text{C} \pm 2\text{K}$ in
 Enterokokkenselektivbouillon

Lagerung: bei $+4^\circ\text{C}$ bis $+8^\circ\text{C}$

Nach Ablauf der Haltbarkeit nicht mehr verwenden und
 vor der Entsorgung desinfizieren.

Datum: 18.12.2020 Freigabe: H. Urbansky

SIMICON GMBH • Sigmund-Riefler-Bogen 19 • D - 81829 München
 Tel.: +49 / (0)89 / 67 33 66 0 • Fax: +49 / (0)89 / 67 33 66 22

No Campione Materiale	25773984 Bio-Indikator STERI BIASCA SIMICON EF - 15 secondi	Data prelievo 1	30.03.2021
Controllo endoscopi	risultati conformi ai requisiti richiesti		
St. aureus	non reperibile in 1 ml		
Enterococchi/Strepto alfa	non reperibile in 1 ml		
Ps. aeruginosa/non ferment	non reperibile in 1 ml		
Enterobatteriacee	non reperibile in 1 ml		

No Campione Materiale	25773985 Bio-Indikator STERI BIASCA SIMICON EF - 30 secondi	Data prelievo 2	30.03.2021
Controllo endoscopi	risultati conformi ai requisiti richiesti		
St. aureus	non reperibile in 1 ml		
Enterococchi/Strepto alfa	non reperibile in 1 ml		
Ps. aeruginosa/non ferment	non reperibile in 1 ml		
Enterobatteriacee	non reperibile in 1 ml		

No Campione Materiale	25773986 Bio-Indikator STERI BIASCA SIMICON EF - 45 secondi	Data prelievo 3	30.03.2021
Controllo endoscopi	risultati conformi ai requisiti richiesti		
St. aureus	non reperibile in 1 ml		
Enterococchi/Strepto alfa	non reperibile in 1 ml		
Ps. aeruginosa/non ferment	non reperibile in 1 ml		

Sampling using biological indicators with a running time of 15 to 60 seconds.
 Analyses performed by an external laboratory with known indicators and
 degree of contamination.



Die Zuordnung der Proben erfolgt durch den Auftraggeber.

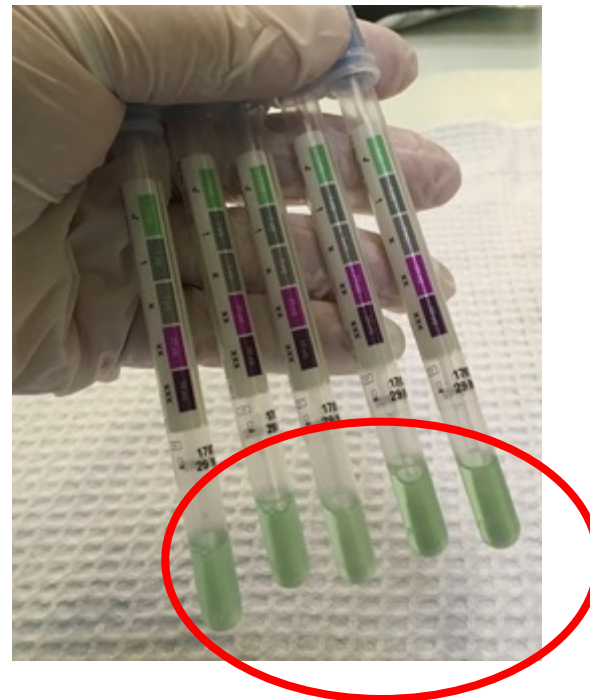
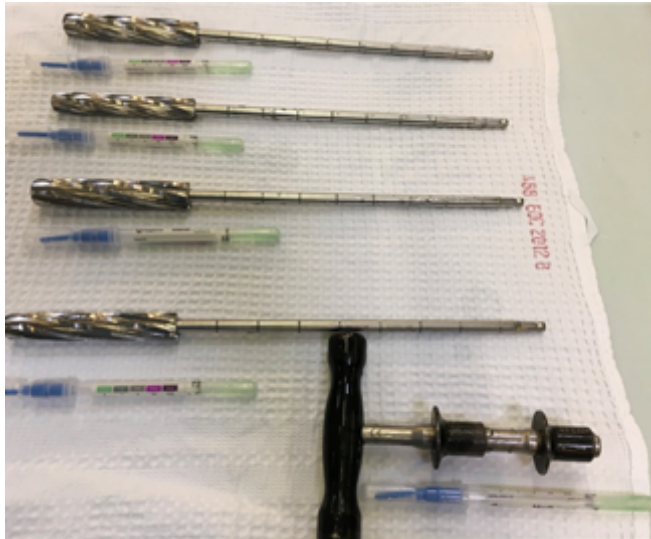
Probe C210319-022-1	Restproteinnachweis			Bemerkungen SMP	Anmerkungen des Validierers
	OPA- Assay"	BCA- Assay"	Hb nach- weisbar		
	µg	µg			
9433	139	26	nein	-	Probica 2
13751	37	-	-	-	-
11769	84	32	nein	-	-
9786	83	58	ja	-	-
11167	212	53	nein	-	-
11753	46	-	-	-	US + LAV
14070	67	-	-	-	-
9358	9	-	-	-	-
9409	25	-	-	-	-
9648	12	-	-	-	-
9324	13	-	-	-	Bica + Lav
14143	19	-	-	-	-
7073	74	-	-	-	-
7800	32	-	-	-	-
11912	10	-	-	-	-
9271	24	-	-	-	Pre + US
11292	26	-	-	-	-
8874	17	-	-	-	-
11075	27	-	-	-	-
9408	22	-	-	-	-
9239	14	-	-	-	Pre/bica
8366	15	-	-	-	-
13777	15	-	-	-	-
8135	15	-	-	-	-
10114	17	-	-	-	-

Use of contaminated clamps analyzed by an external lab.

The results of pre-treatment with sodium bicarbonate and change to WD (cycle interrupted after cleaning) are consistent.

We had to redo the first pure pre-cleaning test... in case we had to learn how to use the device !!

The MDs were stained with sheep blood and protamine sulfate and left to dry for 4 hours.



Protein residue test after pre-cleaning with STK 103-113

Test results still negative

In the first phase of test planning, 3 work breakdown scenarios were defined

❑ 1st scenario with 3 operators

1 operator preparing and loading the baskets

1 operator at STK 103-113

1 operator for STK 103-113 and emptying WD

❑ 2nd scenario with 4 operators

1 operator preparing and loading the baskets

1 operator at STK 103-113

1 operator emptying STK 103-113

1 person at the WD

❑ 3rd scenario with 5 operators

1 operator in charge of receiving the MDs

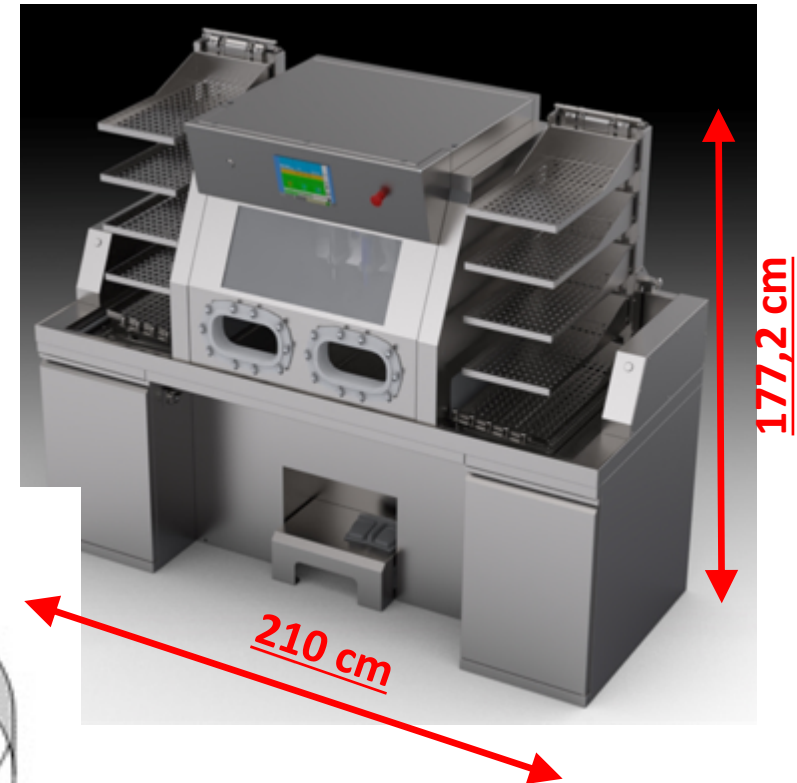
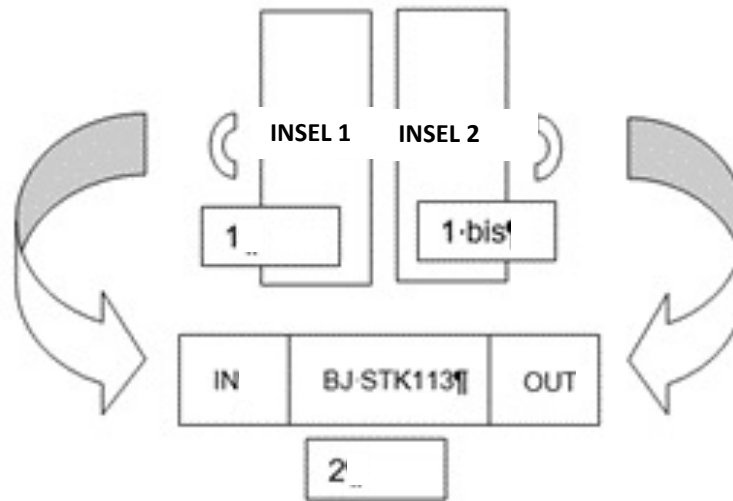
1 operator preparing and loading the baskets

1 operator at STK 103-113

1 operator emptying STK 103-113

1 person at the WD

Diagram scenario 1



The following data were recorded during the test phase (daily and by shift):

- ☐ Number of employees involved
- ☐ Operation time
- ☐ Operation time STK 103-113
- ☐ Cleaning time STK 103-113
- ☐ Number of sets reprocessed per cycle
- ☐ Amount of sodium bicarbonate added
- ☐ Quantity of disinfectant used
- ☐ Number of individual protective measures

Feedback from the technical team monitoring the equipment and proposals from production staff

Centrale dei Servizi Industriali

Sterilizzazione

eoc

M-STE-XY5

Rilevamento problematiche / idee miglioramento Bicarjet SAFE CleanBox

Data: → 1-4-21 Operatore: → Teresa e Arcangelo

X → Rilevamento problematica

X → Proposta miglioramento

La pedaliera continua a spostarsi in quanto le nostre scarpe antinfortunistica hanno le punte molto grandi e arrotondate, i pedali vanno premuti in punta e questo fa spostare la pedaliera

Fissare la pedaliera e procurare dei rialzi di almeno 2 misure differenti. Vedi rapporto ergonomia

Con BicarJet scenario 1		Sett.	M-STE-XY2				
	Colonnati	Lunedì	Martedì	Mercoledì	Giovedì	Venerdì	Sabato
TURNO 1	Data:						
	Tempo Prep. Macchina						
	Tempo Puliz. Macchina						
	Qtà set prioritari						
	Ora inizio:						
	Ora fine:						
	Oper. Prep. Lavaggio						
	Oper. BicarJet						
	Oper. Carico LS						
	Qtà Strumenti						
TURNO 2	Data:						
	Tempo Prep. Macchina						
	Tempo Puliz. Macchina						
	Qtà set prioritari						
	Ora inizio:						
	Ora fine:						
	Oper. Prep. Lavaggio						
	Oper. BicarJet						
	Oper. Carico LS						
	Qtà Strumenti						

Identificare i set trattati nel BicarJet col nastro BLU
 Estrapolare dagli eventi i set trattati col BicarJet tramite l'operatore della preparazione al lavaggio, stampare lista.

Temporary installation for the test.
 The existing pre-cleaning area will of course be converted in the event of a purchase decision.

Images of sodium bicarbonate and disinfectant refills
 for the inside of the tank.

Product approval by :

Dipartimento del territorio

Divisione dell'ambiente

Ufficio della gestione dei rischi ambientali e del suolo



Test of the 3 scenarios defined during the first days.

Result: scenarios 2 and 3 not applicable to our CSSD.

Too much unproductive time for employees at the start and end of the process: not efficient.

For this reason we have focused on the scenario with 3 operators.

- ☐ 1 operator preparing and loading STK 103-113
- ☐ 1 operator in charge of pre-cleaning with STK 103-113
- ☐ 1 operator in charge of emptying STK 103-113 and loading the WD holders

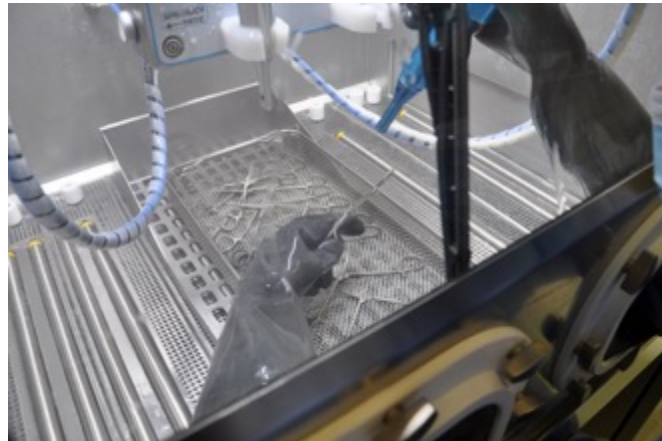


Successful integration of our 3 TDM apprentices in their 3rd year in this project.

MDs divided into baskets as for the ultrasound tank, then positioned on the load support of the STK 103-113 and then introduced into the tank.



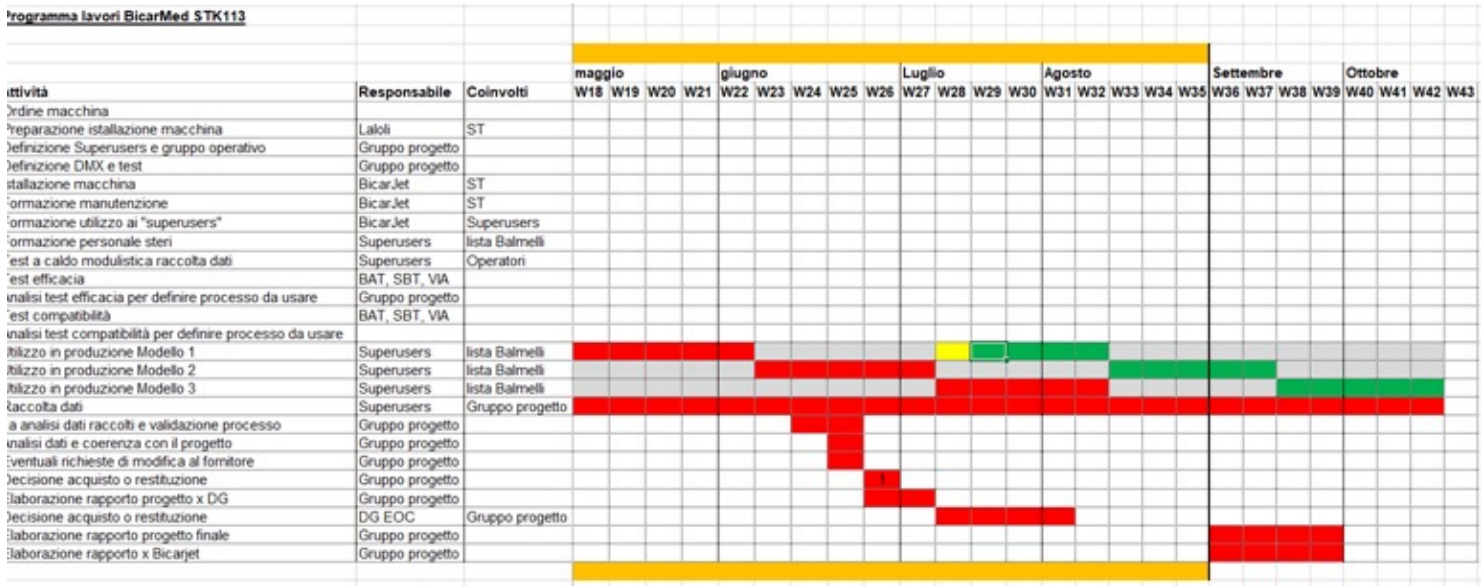
Remote control opens and closes doors and activates basket entry.



The water jet or rather the water jet combined with sodium bicarbonate and air is regulated with a foot pedal.

Tweaking of the test for about 5 months.

- ☐ Part 1 installation and training of the technical staff
- ☐ Laboratory tests
- ☐ Training of shift supervisors
- ☐ Training of operators
- ☐ Production with the 3 scenarios



In production we ended up focusing only on the 3-person scenario that best suited our needs.

We work in CSSD with 3 levels of priority for the return of MDs to the OR

- ☐ 1 return for the next shift
- ☐ 2 return for the 2nd shift (24h)
- ☐ 3 return for the 3rd shift (36h)

OR requests 50% priority 1!

We decided to use STK 103-113 for priority 1 and compare the processing speed with the "traditional" process.

Lista dei lotti in zona pulita							Totale ore ricomposizione: 19		Aggiorna
Trovati 123 lotti (05.10.21 09:54)									
Priorità	Arrivo	Stato di produzione	ID set	Descrizione	Operatore	Clien...	t RIC.		
Prioritario	05.10.21 06:34	IN ZONA PULITA	SET00376718	URETERORENOSCOPIO FLESSIBILE, IN PROVA OBV	Ingegneri G.	OBV	5		
Prioritario	05.10.21 06:34	IN ZONA PULITA	SET00007533	POSA PIG TAIL + URS OBV	Dautaj L.	OBV	11		
Prioritario	05.10.21 06:34	IN ZONA PULITA	SET00015711	VITI LCP 3,5, CORTICALI 2,7/3,5 - SPONGIOSE 4,0	Gandolfi L. A.	OBV	17		
Prioritario	05.10.21 06:34	IN ZONA PULITA	SET00161147	PINZA PER CORPI ESTRANEI OBV	Aliti L.	OBV	3		
Prioritario	05.10.21 06:34	IN ZONA PULITA	SET00170265	TRAPANO FISS. ESTERNO (3 PZ.) OBV	Aliti L.	OBV	3		
Prioritario	05.10.21 06:34	IN ZONA PULITA	SET00178657	TRAPANO A MANO OBV	Aliti L.	OBV	3		
Prioritario	05.10.21 06:34	IN ZONA PULITA	SET00019026	SET AMO OIL	Aliti L.	OIL	23		
Prioritario	05.10.21 06:34	IN ZONA PULITA	SET00145818	CUCCHIAIO PICCOLO CON DENTI	Aliti L.	OIL	3		
Prioritario	05.10.21 06:34	IN RICOMPOSIZIONE	SET00173302	COLIBRI II	Cairolì M.	OIL	27		
Prioritario	05.10.21 06:34	IN ZONA PULITA	SET00203831	COLIBRI II	Aliti L.	OIL	27		
Prioritario	05.10.21 06:34	IN ZONA PULITA	SET00409223	O90 PICCOLA TRAUMA	Ingegneri G.	OIL	29		
Prioritario	05.10.21 06:34	IN ZONA PULITA	SET00413052	O90 PICCOLA TRAUMA	Ingegneri G.	OIL	29		
Prioritario	05.10.21 07:07	IN RICOMPOSIZIONE	SET00016553	BASE GINECOLOGIA OCL	Fazliu L.	OCL	26		
Prioritario	05.10.21 07:07	IN ZONA PULITA	SET00399613	SET EXPEDIUM KUHLEN COMPLETO OCL	Dautaj L.	OCL	18		
Prioritario	05.10.21 07:24	IN ZONA PULITA	SET00000410	DIVARICATORE SPALLA ODL	Dautaj L.	ODL	5		
Prioritario	05.10.21 07:24	IN ZONA PULITA	SET00013443	PLACCA PHILOS Ø 3,5	Dautaj L.	ODL	29		
Prioritario	05.10.21 07:24	IN RICOMPOSIZIONE	SET00013746	PLACCHE METAFISARIE ODL	Lepore C.	ODL	36		
Prioritario	05.10.21 07:24	IN ZONA PULITA	SET00400109	O90 PICCOLA TRAUMA	Ingegneri G.	ODL	29		
Prioritario	05.10.21 07:24	IN ZONA PULITA	SET00400164	O90 PICCOLA TRAUMA	Ingegneri G.	ODL	29		
Prioritario	05.10.21 07:25	IN ZONA PULITA	SET00003234	PICCOLI INTERVENTI PEDIATRIA OSG	Dautaj L.	OSG	32		
Rapido	04.10.21 12:11	IN ZONA PULITA	SET00414474	O90 SET PICCOLO	Lepore C.	OCL	15		
Rapido	04.10.21 16:27	IN ZONA PULITA	SET00000788	SENI PARANASALI OSG	Valente Veludo ...	OSG	28		
Rapido	04.10.21 16:27	IN ZONA PULITA	SET00415348	O90 SUPPLEMENTO SENO	Valente Veludo ...	ODL	8		
Rapido	04.10.21 16:27	IN RICOMPOSIZIONE	SET00002541	SENI PARANASALI OSG	Travieso Cause ...	OSG	28		
Rapido	04.10.21 16:27	IN ZONA PULITA	SET00214358	TROKAR 5.5 + MANDRINO OSG	Valente Veludo ...	OSG	4		

At the same time, we were able to assess the effectiveness of STK 103!

Comparison of processing times

Summary of MDs processed with STK-103-113				
KW	Anz. Set	Arb. Zeit	Anz..MP	Zeit x MP
28	106	17h30	3664	17.1"
29	112	8h25	3447	8.8"
30	125	17h73	4565	15.2"
31	109	10h4	2660	14.0"
32	63	5h4	1129	17.2"
33	122	15h51	3662	15.2"
34	61	11h	1255	31.5"
35	67	10h16	2914	18.6"
Total	765		23296	17.2"

Comparison with current process				(1 shift)
Woche	Anz. Set	Arb. Zeit	Anz..MP	Tempo x MP "
Montag	21	2h08	492	14.6"
Dienstag	9	2h26	193	45.3"
Mittwoch	29	1h43	2074	2.9"
Donnerstag	10	2h11	373	20.3"
Freitag	22	2h58	1311	7.08"
5 Tagen	91	10h46	4443	8.4"

In this case too, we recorded data using the same method.

From the opening of the sets to the loading in WD

1st finding ... with STK 103-113
it takes 2x as long!!but...

All MDs treated with STK 103-113 and processed in WD were perfectly clean.
No MD had to be returned for cleaning.

Cost of consumables?

	Quantity	Price	Total costs
Sodium bicarbonate	64	36	2304
Disinfectant	2	270	540
Customs tax			342
Total costs of consumables			3186 €

	Total costs	Number of MDs	Cost Per MD
Costs per MD	3186	23296	0.14 €

Is it a lot? Is it low? For a final purchase decision the management also takes into account potential savings in terms of repair of MDs due to corrosion.

The next slides show images of MDs treated with STK 103-113.

We immediately noticed that when using STK 103-113 the MDs were absolutely clean in the packaging area.

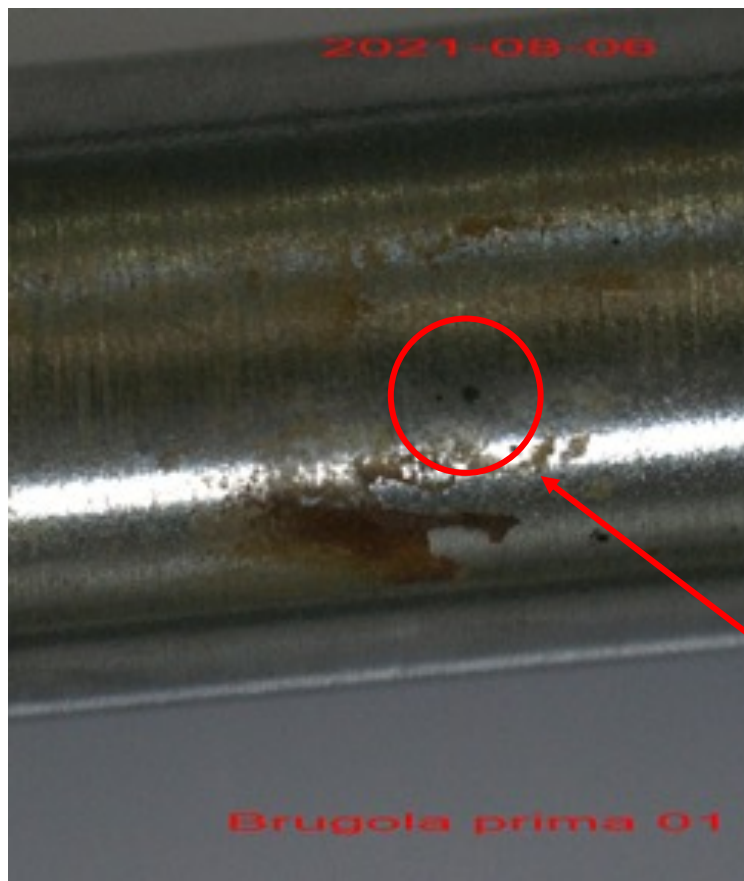
We encountered no problems with the cleaning of the MDs.

On the contrary, it was easier to identify MDs with significant corrosion problems.

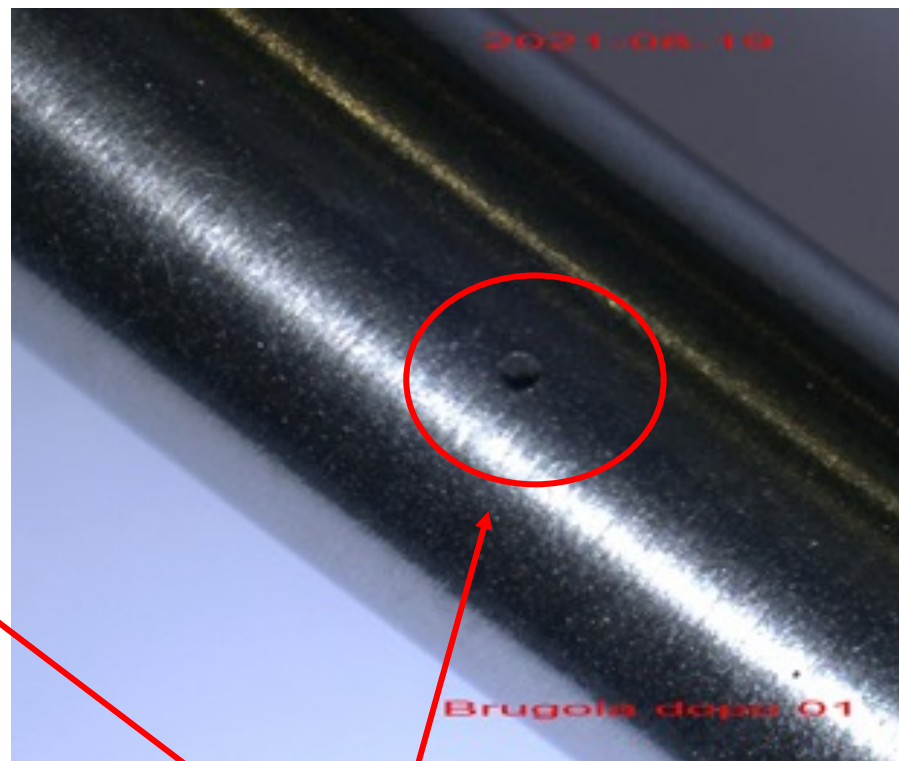
These 3 DMx were processed with the STK 103-113 before being sent to the WD and showed no visible corrosion to the naked eye.

We were able to better detect problems thanks to STK 103-113





Allen key after a normal cycle in WD



It's the same key!

Allen key with pre-cleaning

☐ STK 103-113

☐ Cycle in WD

☐ Steam sterilization

In the case of surface or contact corrosion, it becomes possible to extend the life of the MD.



Example 2

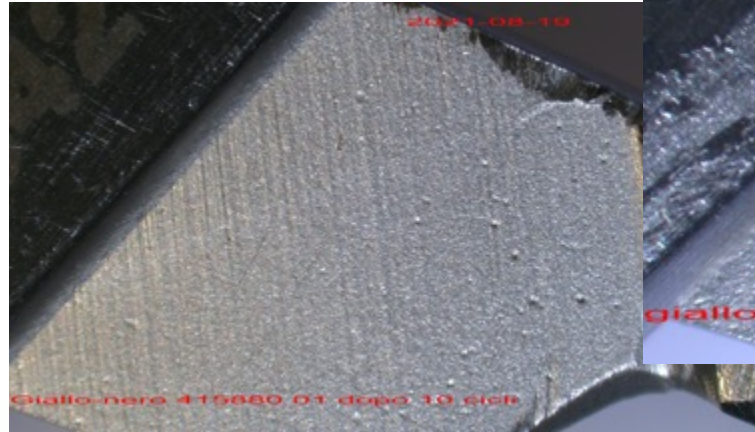
Continuous testing

After 10 reprocessing cycles

STK 103-113

Standard program WD

Steam sterilization



Needle holder after repair +
 normal cycle in WD.
 MD planned for the stock, but...
 look at the state of it...!



Again, the same MD!

Surfaces in much better condition

After 30 reprocessing cycles

STK 103-113

Standard program in WD

Steam sterilization 134°C-18 min.

(not used in OR)

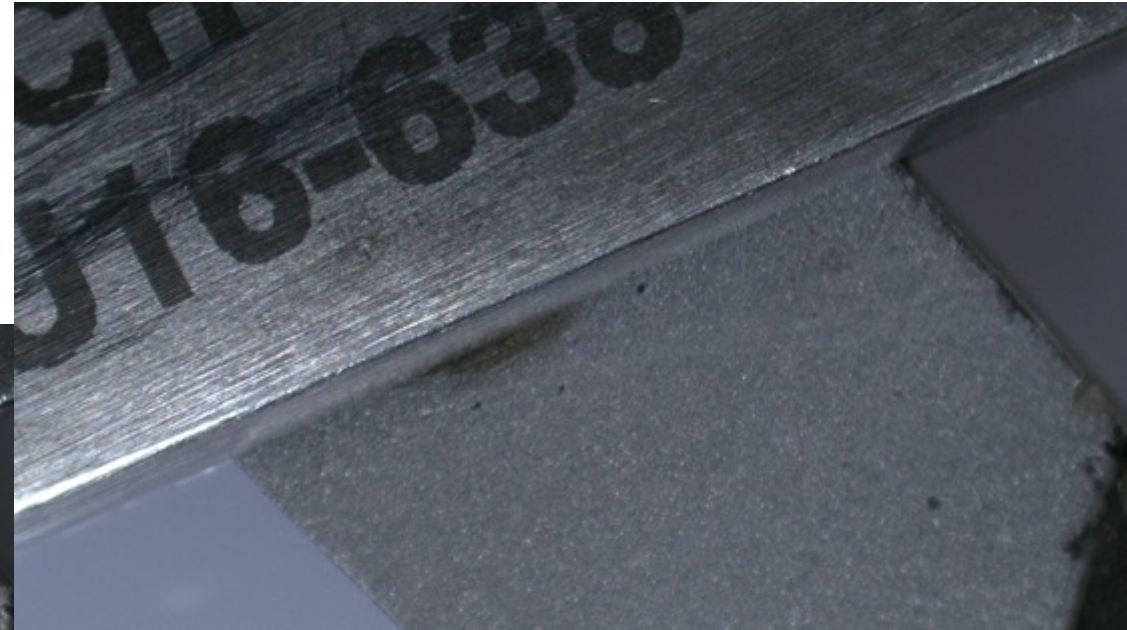
2nd needle holder

After 10 reprocessing cycles

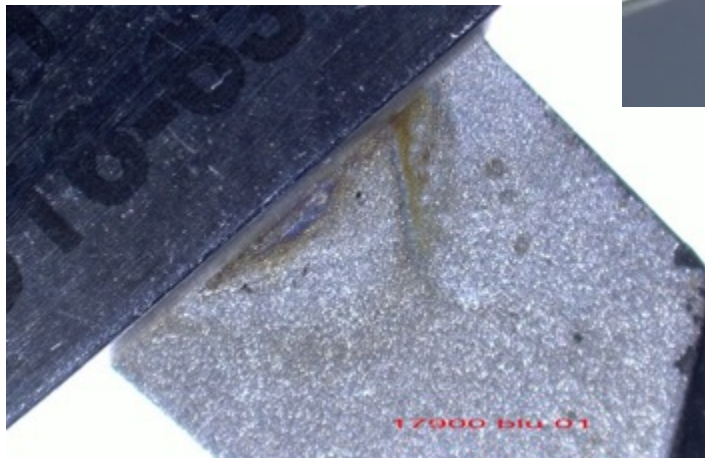
STK 103-113

Standard program in WD

Steam sterilization



Needle holder after repair +
 normal cycle in WD.
 MD planned for the stock, but...
 look at the state of it...!



This test was conducted with 10
 different instruments and the
 result was always convincing.

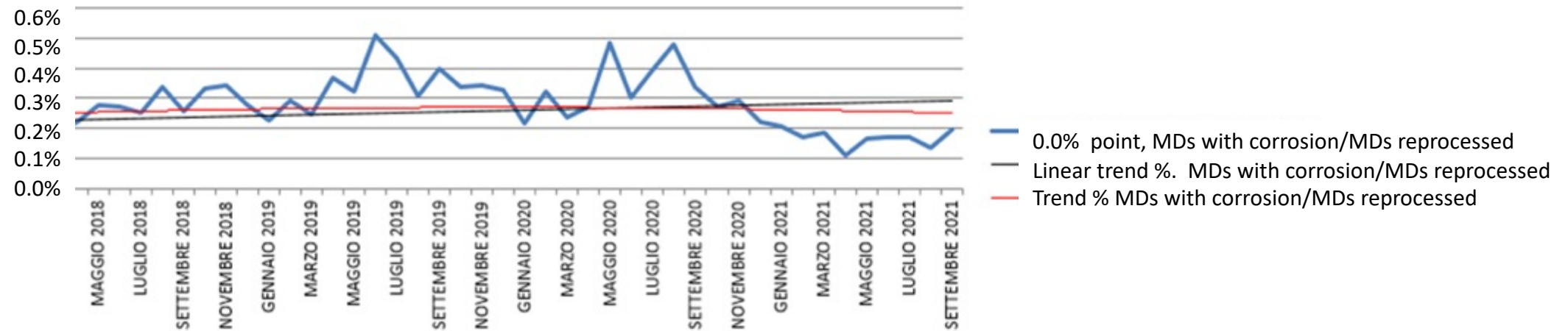
After 30 reprocessing cycles

STK 103-113

WD standard program

Steam sterilization 134°C-18 min.
 (not used in OR)

Evidence of corrosion of MDs processed in CSSD



Currently positive development in terms of corrosion... increasingly rare... certainly not only due to the use of STK 103-113... but we can affirm that the result was at least not negative.

From a technical point of view we can say that pre-cleaning with the STK 103-113 has improved the results!

Advantages

- ☐ Better quality after cleaning in WD
- ☐ Better care of instrument surfaces
- ☐ Far fewer, if any, MDs requiring to be re-cleaned

Disadvantages

- ☐ Slightly higher costs of consumables
- ☐ Longer processing time
- ☐ New organization of the pre-cleaning process (staff must change their habits to some extend)
- ☐ Investment

Comments

- ☐ Longer processing time - yes, but time is saved in repackaging without searching for clean MDs.
- ☐ Higher cost of consumables but less repair (a needle holder costs €20!)
- ☐ New organization, optimization will reduce time and costs

**Thank you very much for
your attention
T. Balmelli
Geneva 17-11-2021**

**In collaboration with
Teresa Sbabo-Milano, shift manager
Antonio Di Iorio, CSSD Manager**

