QUALITY PLUS

nopa® instruments

thank you for choosing
nopa instruments...

...you obviously have good taste

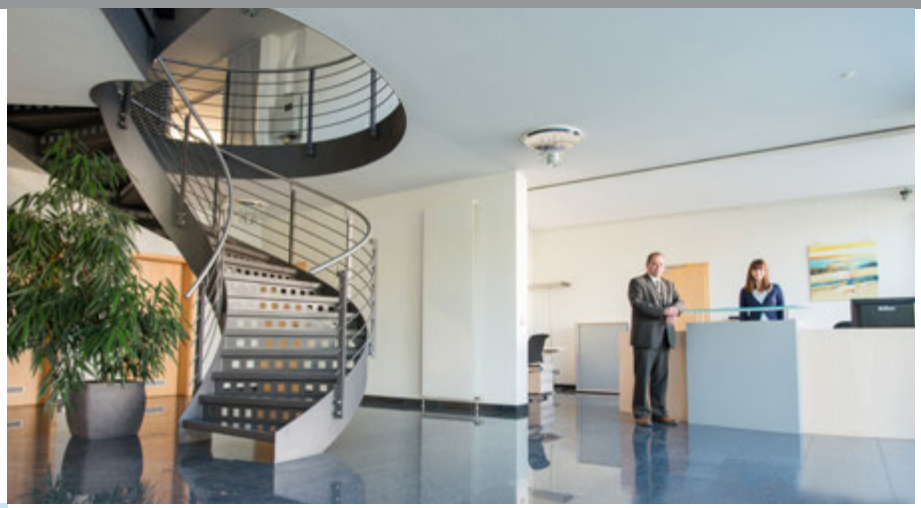
>>

The head office of **nopa instruments** is located in Tuttlingen/Germany, the "World Centre of Medical Technology"

>> Company founded in 1982
>> Company founders **No**rbert **Pa**uli and Monika Pauli
>> Decades of experience in the field of surgical and endoscopic instruments, as well as sterilization containers
>> One of the first companies in its sector to be certified since 1995 according to international standards and norms

>>

QUALITY PLUS



Chamber of Commerce and Industry
Schwarzwald-Baar-Heuberg
(ID No. 36325694)

Chamber of Crafts Konstanz
(Company No. 31659)

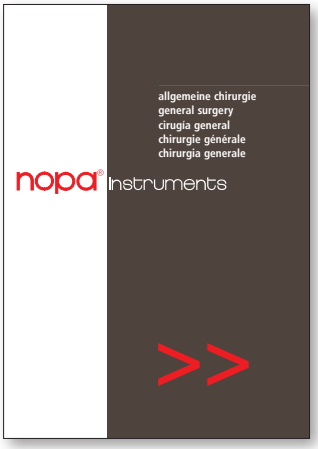
District Court Stuttgart
(Registration No. HRB 450413)

We are **members in different committees** and participate in various scientific studies:

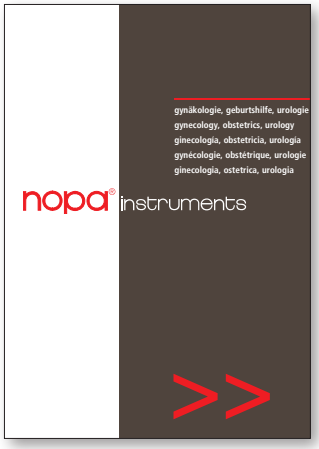
>> Instrument sterilization and cleaning
>> Instrument sterilization
>> Validation processes

PRODUCT RANGE AND CATALOGUES

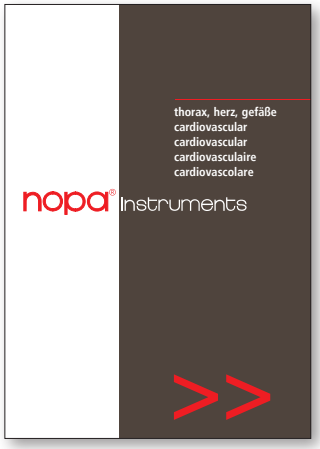
Our product catalogues can be found in electronic form on our website.
We are also happy to make our catalogues available to you as printed books.



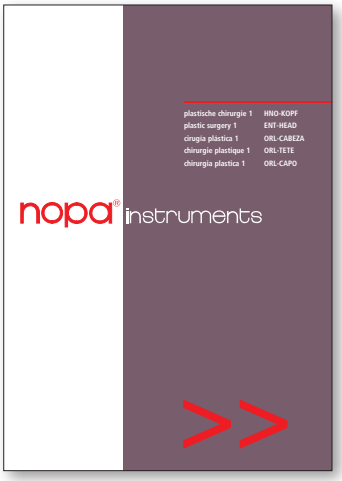
A-K general surgery
illustrated on 664 pages



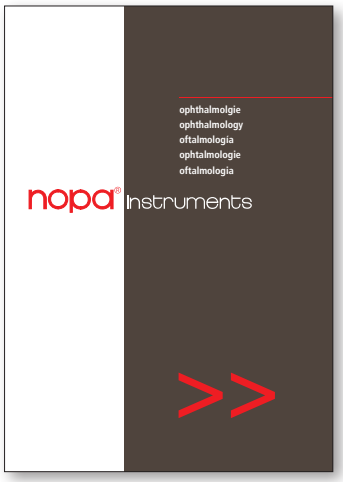
KB-KC gynecology, obstetrics and
urology, illustrated on 574 pages



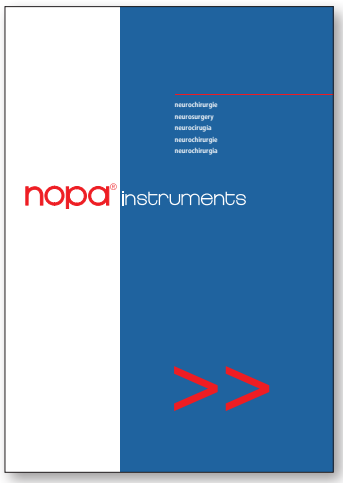
KK cardiovascular
illustrated on 380 pages



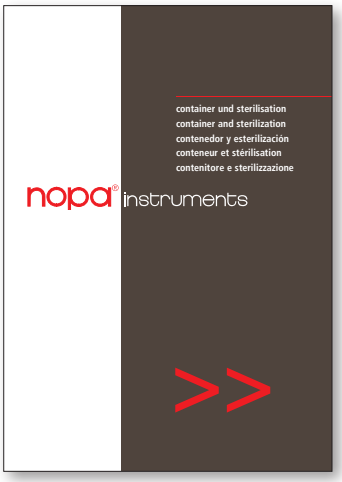
KL-KO plastic surgery ENT-HEAD
illustrated on 500 pages



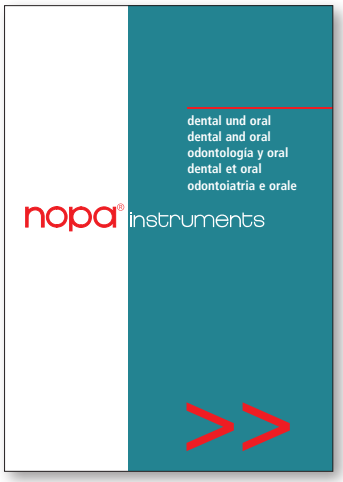
KP ophthalmology
illustrated on 238 pages



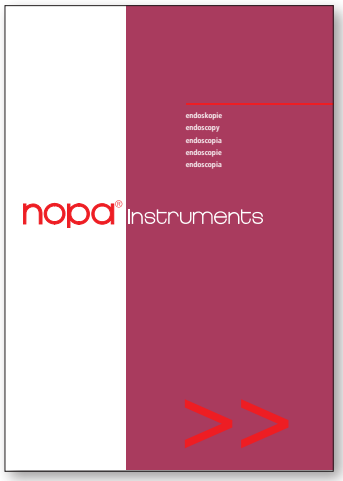
KS neuro surgery
illustrated on 201 pages



KYE container and sterilization
illustrated on 136 pages



P dental and oral
illustrated on 404 pages



X endoscopy
illustrated on 266 pages

Our product range includes

16,000 products

sales in **over 120 countries**

CE-CERTIFICATION

nopa instruments has a quality management system in accordance with the standard ISO 13485, based on the legislation 93/42/EEC of 14.06.1993 for medical instruments.

Certificate

mdc medical device certification GmbH
certifies that

nopa instruments
nopa instruments Medizintechnik GmbH
Weilatten 7-9
78532 Tuttlingen
Germany

for the scope

development and design, production and distribution of surgical, dental and HF instruments with accessories, endoscopy materials, needles, sterilization containers

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 13485:2012 + AC:2012 - ISO 13485:2003 + Cor. 1:2009

Valid from	2015-06-25
Valid until	2018-06-24
Registration no.	D1121700019
Report no.	P15-00527-44480
Stuttgart	2015-06-25

Head of Certification Body

EC Certificate

edical device certification GmbH
Notified Body 0483
herewith certifies that

nstruments Medizintechnik GmbH
Weilatten 7 - 9
78532 Tuttlingen
Germany

for the scope

n and irrigation cannulae (10-566), Klasse IIa;
py forceps with HF connection (11-502), class IIb

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system meets all requirements according to

Annex II – excluding Section 4
of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2015-06-25
Valid until	2020-06-24
Registration no.	D1121700020
Report no.	P15-00527-44484
Stuttgart	2015-06-25

Head of Certification Body

Our complete certificates are available as download on our website

the nopa philosophy
CERTIFICATION
Quality Plus

Please ask for
EC-Declaration of conformity

EG-Konformitätserklärung
EC-Declaration of conformity

Anbieter: *Supplier*: nopa instruments Medizintechnik GmbH

Anschrift: *Address*: Weilatten 7-9, 78532 Tuttlingen

Medizinprodukt: *Medical Device*: wiederverwendbare chirurgische Instrumente
reusable surgical instruments
gemäss Anlage 1 Produktgruppenliste
see attachment 1 product group list
ab Fertigungsdatum 01.01.2010
bis Fertigungsdatum 24.06.2018

Wir erklären in alleiniger Verantwortung: Das oben beschriebene Medizinprodukt ist konform mit:
We declare under sole responsibility: The medical device described above is in conformity with:

Dokument-Nr. *Document No.*	Titel (nur harmonisierte Normen) *Title*	Ausgabe/ Ausgabedatum *Edition / Date of issue*
93/42/EWG	Richtlinie 93/42/EWG des Rates über Medizinprodukte Anhang VII *Council Directive 93/42/EEC concerning medical devices App. VII*	14.06.1993
2007/47/EG	Richtlinie 2007/47/EG des Europäischen Parlaments und des Rates *Council Directive 2007/47/EG of the European Parliament and of The council*	05.09.2007

Tuttlingen, 22.06.2015

Stefan Kappeler, QMB
(Name, Funktion / *Name, Function*)

(Unterschrift / *Signature*)

FB Konformitätserklärung Klasse 1

tgruppenliste
duct group list

Produktgruppen-Bezeichnung *Product group description*	UMDNS-Nr.	Risikoklasse	Regel
Klemmen / *Hemostats*	10861	1	6
Pinzetten / *Forceps*	14257	1	6
Scheren / *Scissors*	13480	1	6
Skalpelle / *Scalpels*	12252	1	6
Nadelhalter / *Needle holders*	12726	1	6
Tupferzangen / *Sponge forceps*	11791	1	6
Wundhaken / *Retractors*	13373	1	6
Sonden / *Sondes*	13117	1	6
Verband / *Dressing*	13708	1	6
Kanülen / *Special neddles*	12729	1	6
Narkose / *Anaesthesia*	12293	1	6
Diagnostik / *Diagnostics*	14255	1	6
Orthopädie / *Orthopaedic*	11507	1	6
Gynäkologie / *Gynecology*	11788	1	6
Urologie / *Urology*	17633	1	6
DE/CA39/648/67 KD	Darm, Magen, Mastdarm / *Instestines, Stomach, Rectum*	13665	1	6
DE/CA39/648/32 KI	Mammaplastik / *Mammaplasty*	13373	1	6
DE/CA39/648/11-12 KK	Herz, Thorax / *Cardio vascular*	10838	1	6
DE/CA39/648/76-77 KL	Mund, Zunge, Tonsillen/ *Oral instruments, Tonsils*	15672	1	6
DE/CA39/648/82 KM	Otologie / *Otology*	13662	1	6
DE/CA39/648/83 KO	Rhinologie / *Rhinology*	13632	1	6
DE/CA39/648/72 KS	Clips/clip	10898	1	6
DE/CA39/648/32 KS	Säge/saw	13448	1	6
DE/CA39/648/30 KS	Zange / *Forceps*	11774	1	6
DE/CA39/648/85 KS	Haken / *Hook*	12028	1	6
DE/CA39/648/13 KS	Zange Fixation / *Forceps fixation*	11781	1	6
DE/CA39/648/25 KS	Mikrochirurgieinstrument / *Micro surgery instrument*	15621	1	6
DE/CA39/648/64 KS	Spreitzer / *Spreader*	13707	1	6
DE/CA39/648/89 KS	Stanze / *Punch*	13228	1	6
DE/CA39/648/94 KS	Elevatorium / *Elevator*	11507	1	6
DE/CA39/648/95 KU	Verschiedenes / *Various Items*	15561	1	6

Stand 22.06.2015

Dateiname	Revision	erstellt am	von	zuletzt geändert am	von	Seite
FB Produktgruppenliste Klasse1.doc	A	21.03.2010	Kappeler	09.04.2013		

Study by the **University Hospital of Freiburg**:
Comparison of nopa instruments to the instruments used in the clinic

UNIVERSITÄTS KLINIKUM FREIBURG
STUDIENZENTRUM

MPE – nopa instruments Medizintechnik GmbH

Title of the study: Market preference analysis (MPE-nopa) Evaluation of different instruments from the company nopa instruments Medizintechnik GmbH
Client: nopa instruments, Medizintechnik GmbH, Weilatten 7-9, 78532 Tuttlingen
Test product(s): HALSTED-MOSQUITO FCPS STR 12,5 CM CRILE-RANKIN FORCEPS CVD 16.0 CM BACKHAUS TOWEL FORCEPS 8,0 CM STANDARD DRESSING FORCEPS STR 14.5 CM STANDARD TISSUE FCPS. 1X2 T STR 14,5 CM STANDARD OPER.SCS. STR.SH/BL 14.5 CM MAYO DISS.SCS TUC STR BL/BL 17.0 CM METZENBAUM-NELSON SCS CVD BL/BL 18.0 CM SCALPEL HANDLE NO.3 SCALPEL HANDLE NO.4 CRILE-WOOD NEEDLE HOLDER TUC 15.0 CM MAYO-HEGAR NEEDLE HOLDER TUC 18.0 CM CUSHING RECTRACTOR 12 MM 20.0 CM VOLKMANN RETR.BLUNT 3 PRONGS 21.5 CM NOPA E-CONTAINER 285x280x100MM, RED WIRE BASKET, 255 X 245 X 50 MM
Objective of the study: Evaluation of handling during surgery / application of the aforementioned surgical products
Study design: Survey of OP personnel by means of a questionnaire **Case number (planned and analysed):** N=25 (25 different applications in the study period)
Study procedure: Survey of OP personnel by means of a questionnaire with regard to the evaluation of different instruments from the company nopa-instruments **Study conducted by:** University Clinic Freiburg, Study Centre
Date of the beginning of the study: 01.04.2013 **Date of completion of the study:** 31.12.2013
Summary of the results: If an average value is derived from the individual assessments, the products used reach a value of 6.16 (based on 0 = bad, 10 = very good). See reverse for details, diagram 1
Conclusions: In all, the nopa instruments were assessed by the participants to be equal in value to existing instruments. On a scale from 0-10, both the evaluation of almost all of the instruments and the overall rating were above the average value of 5.0, with the highest value even reaching 7.43. See reverse for details, diagram 2 and diagram 3

Concluding report MPE nopa instruments, Version 01, 10.02.2014 Page 1 of 2

UNIVERSITÄTS KLINIKUM FREIBURG
STUDIENZENTRUM

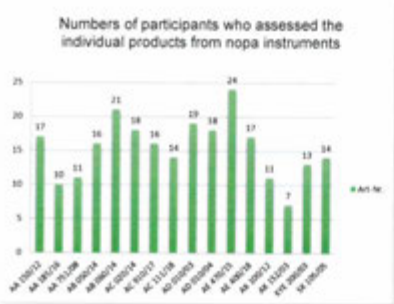


Diagram 1

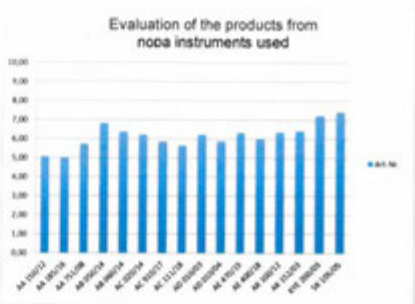


Diagram 2

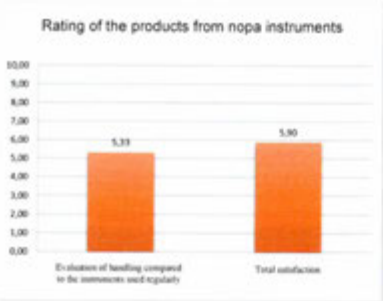


Diagram 3

Authors:

Birgit Grotejohann Project coordinator Study Centre	Signature	Freiburg 26.02.2014 Place, date
Julia Maurer Project assistant Study Centre	Signature	Freiburg, 26.02.2014 Place, date
Erik Hummel Managing Director	Signature	Tuttlingen 28.02.2014 Place, date

CORPORATE BRANDS

nopa® instruments

nopa® TUC

SUPER CUT TUC

SUPER CUT

ATRAUMA nopa®

nopa® DIAMOND

POSTERS

Poster ENT

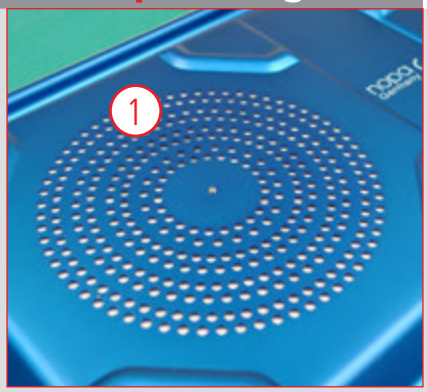
Poster Sterilization

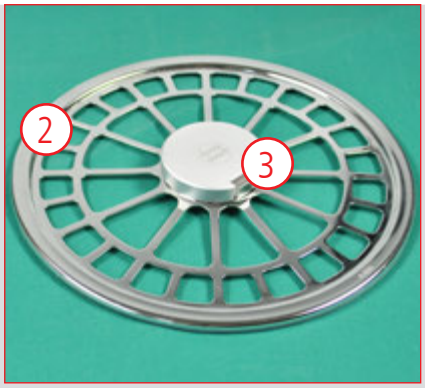
Poster Instruments

nopa instruments posters in the format 50 x 70 cm are also available for your exhibition space..

Validation certificate
refer to page 14

Our **nopa** Design



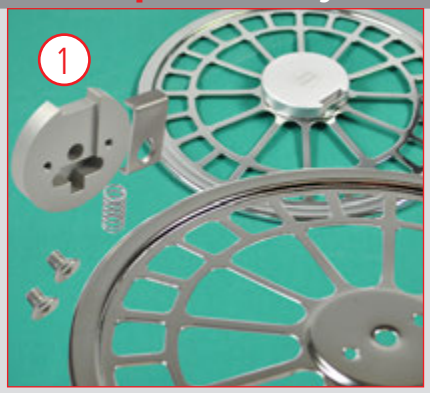


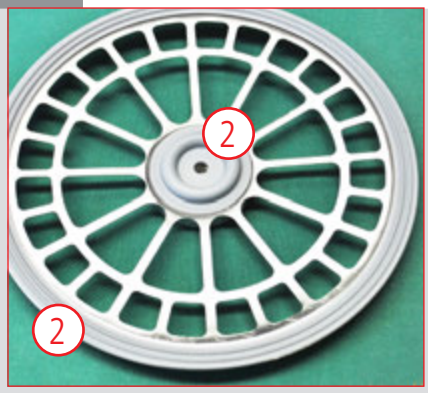
1. Round perforations in the lid
2. Filter holder with proven design
3. Proprietary and protected closure system
4. Special **nopa** closure
5. Silicone covered and ergonomically shaped handles
6. Prominent black, continuous front panel
7. Corner protection

On request, we will mark the container with your company name or logo by laser.

the nopa philosophy
STERILIZATION
Quality Plus

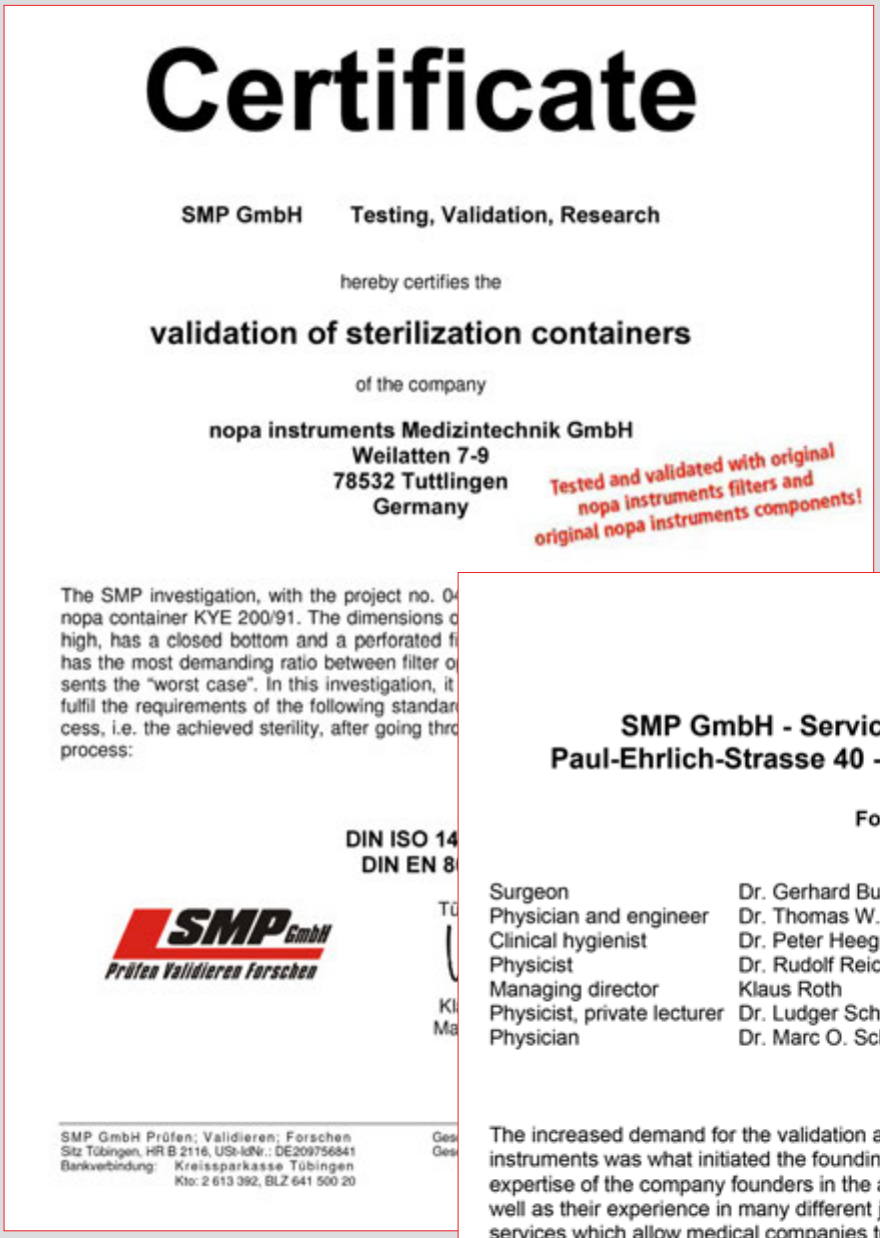
Our **nopa** Quality





1. Assembling of filter holder
2. Gluing of inner and outer ring onto the filter holder
3. Gluing of the silicone seal into the inside of the container lid

Implemented and checked by our highly qualified team



Certificate

SMP GmbH Testing, Validation, Research

hereby certifies the

validation of sterilization containers

of the company

nopa instruments Medizintechnik GmbH
Weilatten 7-9
78532 Tuttlingen
Germany

Tested and validated with original nopa instruments filters and original nopa instruments components!

The SMP investigation, with the project no. 0
nopa container KYE 200/91. The dimensions o
high, has a closed bottom and a perforated fi
has the most demanding ratio between filter o
sents the "worst case". In this investigation, it
fulfil the requirements of the following standar
cess, i.e. the achieved sterility, after going thro
process:

DIN ISO 14
DIN EN 8

SMP GmbH Prüfen; Validieren; Forschen
Sitz Tübingen, HR B 2116, USt-IdNr.: DE209756841
Bankverbindung: Kreissparkasse Tübingen
Kto: 2 613 392, BLZ 641 500 20

Sterilization certificate available as download on our website.

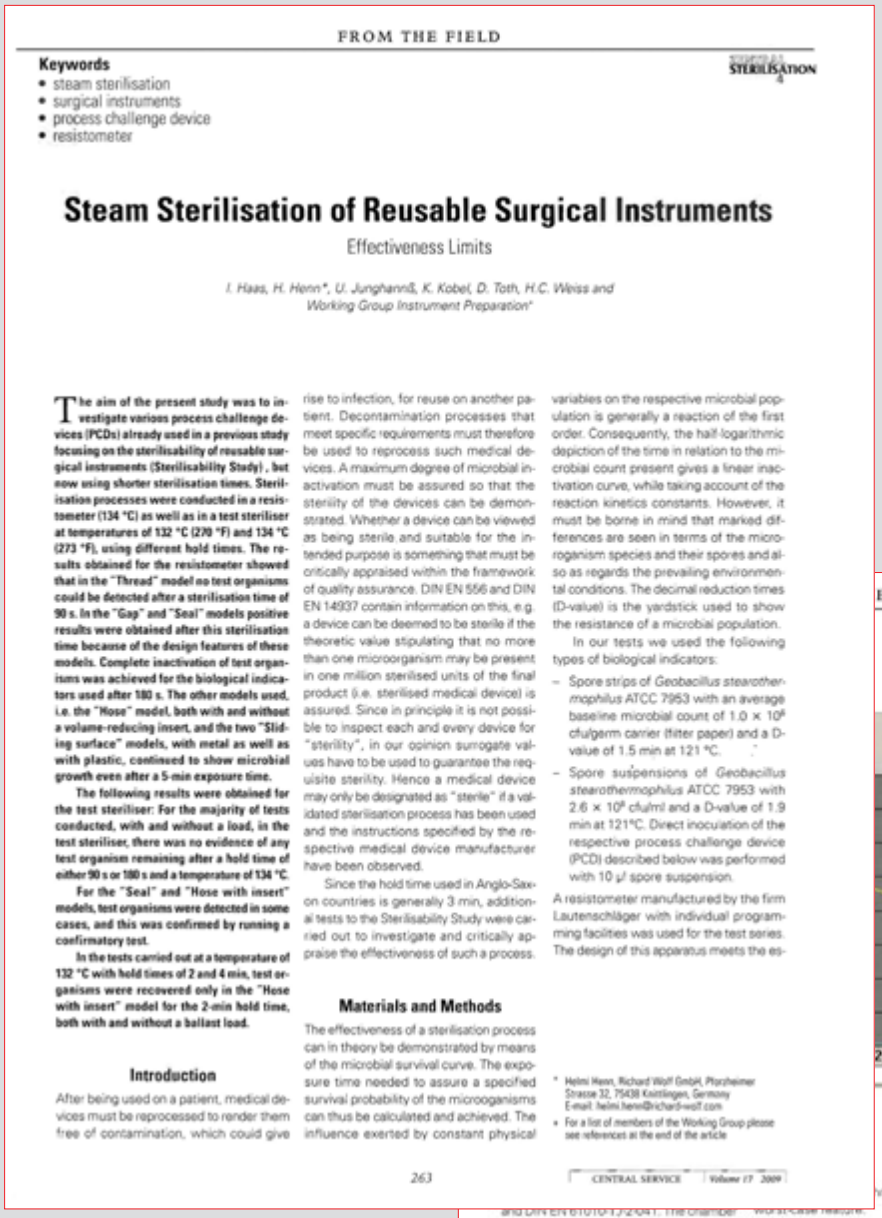
SMP GmbH - Service for medical products
Paul-Ehrlich-Strasse 40 - 72076 Tübingen – Germany

Founders

Surgeon	Dr. Gerhard Bueß / University of Tübingen
Physician and engineer	Dr. Thomas W. Fengler
Clinical hygienist	Dr. Peter Heeg / University of Tübingen
Physicist	Dr. Rudolf Reichl
Managing director	Klaus Roth
Physicist, private lecturer	Dr. Ludger Schnieder
Physician	Dr. Marc O. Schurr

The increased demand for the validation and testing of cleaning processes for surgical instruments was what initiated the founding of SMP GmbH. Based on the skilled expertise of the company founders in the area of surgical instruments and hygiene, as well as their experience in many different joint research projects, SMP GmbH offers services which allow medical companies to make substantiated statements about their products in the area of reprocessing and hygiene.

the nopa philosophy
VALIDATION
Quality Plus



FROM THE FIELD

Keywords
- steam sterilisation
- surgical instruments
- process challenge device
- resistometer

Steam Sterilisation of Reusable Surgical Instruments

Effectiveness Limits

I. Haas, H. Henn, U. Junghanns, K. Kobel, D. Toth, H.C. Weiss and Working Group Instrument Preparation**

The aim of the present study was to investigate various process challenge devices (PCDs) already used in a previous study focusing on the sterilisability of reusable surgical instruments (Sterilisability Study), but now using shorter sterilisation times. Sterilisation processes were conducted in a resistometer (134 °C) as well as in a test steriliser at temperatures of 132 °C (270 °F) and 134 °C (273 °F), using different hold times. The results obtained for the resistometer showed that in the "Thread" model no test organisms could be detected after a sterilisation time of 90 s. In the "Gap" and "Seal" models positive results were obtained after this sterilisation time because of the design features of these models. Complete inactivation of test organisms was achieved for the biological indicators used after 180 s. The other models used, i.e. the "Hose" model, both with and without a volume-reducing insert, and the two "Sliding surface" models, with metal as well as with plastic, continued to show microbial growth even after a 5-min exposure time.

The following results were obtained for the test steriliser: For the majority of tests conducted, with and without a load, in the test steriliser, there was no evidence of any test organism remaining after a hold time of either 90 s or 180 s and a temperature of 134 °C.

For the "Seal" and "Hose with insert" models, test organisms were detected in some cases, and this was confirmed by running a confirmatory test.

In the tests carried out at a temperature of 132 °C with hold times of 2 and 4 min, test organisms were recovered only in the "Hose with insert" model for the 2-min hold time, both with and without a ballast load.

Introduction

After being used on a patient, medical devices must be reprocessed to render them free of contamination, which could give rise to infection, for reuse on another patient. Decontamination processes that meet specific requirements must therefore be used to reprocess such medical devices. A maximum degree of microbial inactivation must be assured so that the sterility of the devices can be demonstrated. Whether a device can be viewed as being sterile and suitable for the intended purpose is something that must be critically appraised within the framework of quality assurance. DIN EN 556 and DIN EN 14937 contain information on this, e.g. a device can be deemed to be sterile if the theoretic value stipulating that no more than one microorganism may be present in one million sterilised units of the final product (i.e. sterilised medical device) is assured. Since in principle it is not possible to inspect each and every device for "sterility", in our opinion surrogate values have to be used to guarantee the requisite sterility. Hence a medical device may only be designated as "sterile" if a validated sterilisation process has been used and the instructions specified by the respective medical device manufacturer have been observed.

Since the hold time used in Anglo-Saxon countries is generally 3 min, additional tests to the Sterilisability Study were carried out to investigate and critically appraise the effectiveness of such a process.

Materials and Methods

The effectiveness of a sterilisation process can in theory be demonstrated by means of the microbial survival curve. The exposure time needed to assure a specified survival probability of the microorganisms can thus be calculated and achieved. The influence exerted by constant physical variables on the respective microbial population is generally a reaction of the first order. Consequently, the half-logarithmic depiction of the time in relation to the microbial count present gives a linear inactivation curve, while taking account of the reaction kinetics constants. However, it must be borne in mind that marked differences are seen in terms of the microorganism species and their spores and also as regards the prevailing environmental conditions. The decimal reduction times (D-value) is the yardstick used to show the resistance of a microbial population.

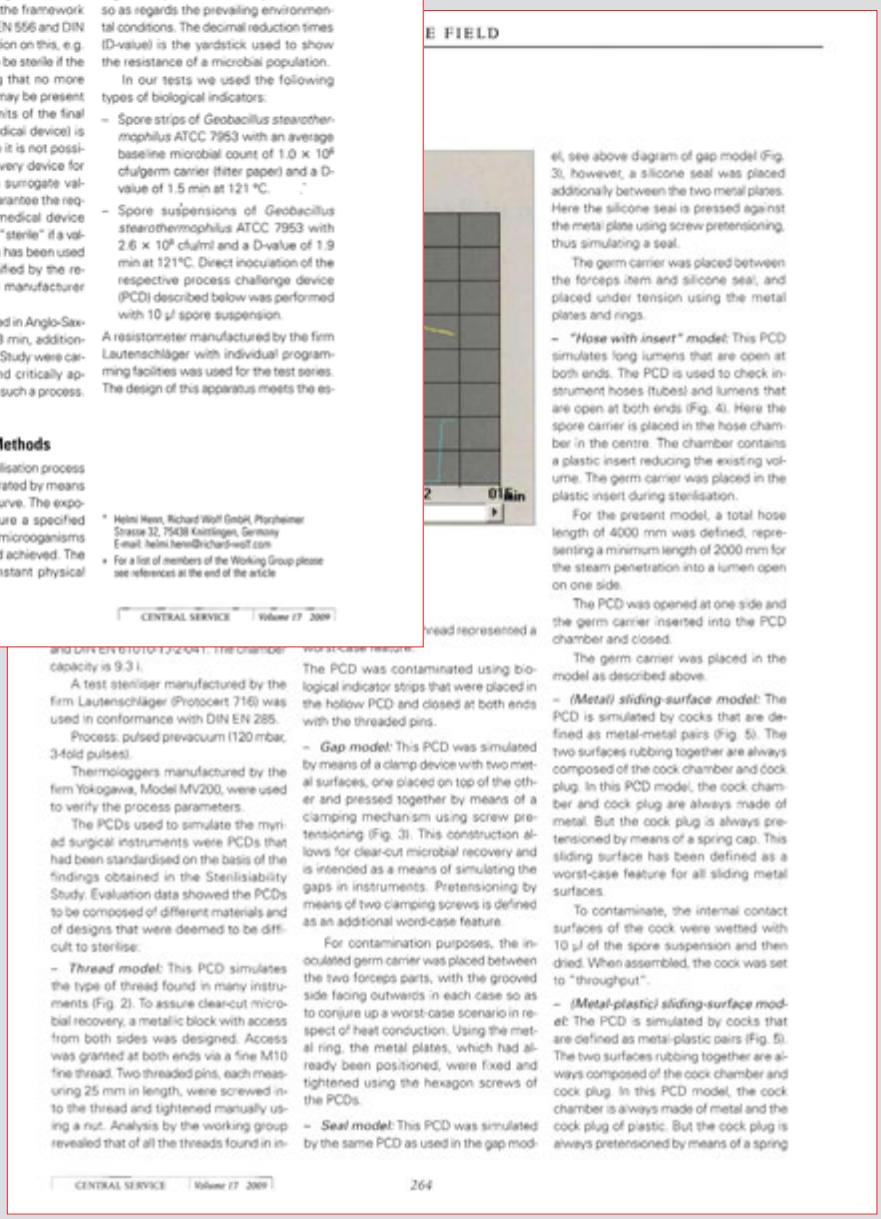
In our tests we used the following types of biological indicators:

- Spore strips of *Geobacillus stearothermophilus* ATCC 7953 with an average baseline microbial count of 1.0×10^6 cfu/germ carrier (filter paper) and a D-value of 1.5 min at 121 °C.
- Spore suspensions of *Geobacillus stearothermophilus* ATCC 7953 with 2.6×10^8 cfu/ml and a D-value of 1.9 min at 121°C. Direct inoculation of the respective process challenge device (PCD) described below was performed with 10 µl spore suspension.

A resistometer manufactured by the firm Lautenschläger with individual programming facilities was used for the test series. The design of this apparatus meets the es-

* Helmi Henn, Richard Wolf GmbH, Pforzheimer Strasse 32, 75438 Knittlingen, Germany
E-mail: helmi.henn@richard-wolf.com

* For a list of members of the Working Group please see references at the end of the article



E FIELD

hread represented a

capacity is 9.3 l.

A test steriliser manufactured by the firm Lautenschläger (Protocert 716) was used in conformance with DIN EN 285.

Process: pulsed prevacuum (120 mbar, 3-fold pulses).

Thermologgers manufactured by the firm Yokogawa, Model MV200, were used to verify the process parameters.

The PCDs used to simulate the myriad surgical instruments were PCDs that had been standardised on the basis of the findings obtained in the Sterilisability Study. Evaluation data showed the PCDs to be composed of different materials and of designs that were deemed to be difficult to sterilise:

– ***Thread model:*** This PCD simulates the type of thread found in many instruments (Fig. 2). To assure clear-cut microbial recovery, a metallic block with access from both sides was designed. Access was granted at both ends via a fine M10 fine thread. Two threaded pins, each measuring 25 mm in length, were screwed into the thread and tightened manually using a nut. Analysis by the working group revealed that of all the threads found in in-

The PCD was contaminated using biological indicator strips that were placed in the hollow PCD and closed at both ends with the threaded pins.

– ***Gap model:*** This PCD was simulated by means of a clamp device with two metal surfaces, one placed on top of the other and pressed together by means of a clamping mechanism using screw pretensioning (Fig. 3). This construction allows for clear-cut microbial recovery and is intended as a means of simulating the gaps in instruments. Pretensioning by means of two clamping screws is defined as an additional word-case feature.

For contamination purposes, the inoculated germ carrier was placed between the two forceps parts, with the grooved side facing outwards in each case so as to conjure up a worst-case scenario in respect of heat conduction. Using the metal ring, the metal plates, which had already been positioned, were fixed and tightened using the hexagon screws of the PCDs.

– ***Seal model:*** This PCD was simulated by the same PCD as used in the gap model, see above diagram of gap model (Fig. 3), however, a silicone seal was placed additionally between the two metal plates. Here the silicone seal is pressed against the metal plate using screw pretensioning, thus simulating a seal.

The germ carrier was placed between the forceps item and silicone seal, and placed under tension using the metal plates and rings.

– ***"Hose with insert" model:*** This PCD simulates long lumens that are open at both ends. The PCD is used to check instrument hoses (tubes) and lumens that are open at both ends (Fig. 4). Here the spore carrier is placed in the hose chamber in the centre. The chamber contains a plastic insert reducing the existing volume. The germ carrier was placed in the plastic insert during sterilisation.

For the present model, a total hose length of 4000 mm was defined, representing a minimum length of 2000 mm for the steam penetration into a lumen open on one side.

The PCD was opened at one side and the germ carrier inserted into the PCD chamber and closed.

The germ carrier was placed in the model as described above.

– ***(Metal) sliding-surface model:*** The PCD is simulated by cocks that are defined as metal-metal pairs (Fig. 5). The two surfaces rubbing together are always composed of the cock chamber and cock plug. In this PCD model, the cock chamber and cock plug are always made of metal. But the cock plug is always pretensioned by means of a spring cap. This sliding surface has been defined as a worst-case feature for all sliding metal surfaces.

To contaminate, the internal contact surfaces of the cock were wetted with 10 µl of the spore suspension and then dried. When assembled, the cock was set to "throughput".

– ***(Metal-plastic) sliding-surface model:*** The PCD is simulated by cocks that are defined as metal-plastic pairs (Fig. 5). The two surfaces rubbing together are always composed of the cock chamber and cock plug. In this PCD model, the cock chamber is always made of metal and the cock plug of plastic. But the cock plug is always pretensioned by means of a spring

Analysis to determine the sterilization time. Performed by the working group "Preparation of surgical instrumentarium".

nopa instruments was a member of this working group.

Complete document (5 pages) is available as download on our website.

DIN 58298:2010-09

Product Group	Elevators/Raspatories	Forceps	Scissors	Ring Forceps / Pliers	Bone Cutting Forceps/Bone Rongeurs/Bone Punches	Shank Forceps / Pliers	Conchotomes	Scalpels / Knives	Retractors
Group of nopa Item Numbers	KA,KO, PF,PI, PS,PT	AB	AC	AA,AB,AE, AF,AM,AP, KD,KA,KB, KC,KD,KK, KL,KM,KO, KS,PV,XK,	KA,KO	AM, KA,KB, KM,KS KU,PA, PB,PT, PU,PV,	KA,KO	AD,KA, KL,KM, KO,KS, KU,	AK,AP, KA,KB, KD,KI, KL,KM, KO,KS

Code letter according to DIN EN ISO 7153-1	Material Number according to DIN EN 10088-1	Material Symbol according to DIN EN 1088-1	Hardness in Rockwell	Application								
B	1.4021	X20Cr13	42 - 50	x	x	x	x	x	x	x		x
A	1.4024	X15Cr13	40 - 48		x		x		x			x
D	1.4034	X46Cr13	50 - 58	x		x		x		x	x	
H	1.4117	X38CrMoV15	50 - 58	x		x		x		x	x	
N	1.4305	X8CrNiS18-9										x
M	1.4301	X5CrNi18-10										x
P	1.4401	X5CrNiMo17-12-2				x	x					x

EN ISO 7153-1:2000

	C	Si, max	Mn, max	P, max	S	Cr	Mo	N
A	0,09 - 0,15	1	1	0,04	0,03 max	11,5 - 13,5		1 m
B	0,16 - 0,25	1	1	0,04	0,03 max	12 - 14		1 m
D	0,42 - 0,50	1	1	0,04	0,03 max	12,5 - 14,5		1 m
H	0,35 - 0,40	1	1	0,045	0,03 max	14 - 15	0,4 - 0,6	
M	0,07 max	1	2	0,045	0,03 max	17 - 19		8 -
N	0,12 max	1	2	0,06	0,15 - 0,35	17 - 19		8 -
P	0,07 max	1	2	0,045 max	0,03 max	16,5 - 18,5	2 - 2,5	10,5 -

material_A_en

overview of the high quality materials used

the nopa philosophy
MATERIAL
Quality Plus

opa® instruments

Probes / Trocars / Suction Tubes	Chisels / Bone Curettes	Mallets	Needleholder	Handle (hollow)	Handle (solid)
AL, AO,	KA,KB, KC,KL, KM,KO				
XK, KB,	KU,PK, PM,XM	AR, KM,KO	AE,KS	AE, AK,	AK,
x	x		x		
x			x		
	x				
	x				
x	x	x			x
x				x	
x					

i	Div	DIN10088-1/AISI F899
ax		1.4024 / 410
ax		1.4021 / 420A
ax		1.4034 / 420C
	V:0,1 - 0,15	1.4117 / 420B
11		1.4301 / 304
10		1.4305 / 303
13,5		1.4401 / 316

22.09.2015

Dr.-Ing.
storz
Werkstoffberatung

Storz Jakobshäuschen 6 42655 Solingen

truments Medizintechnik GmbH
n 7 - 9

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Stadt-Sparkasse-Solingen
(BLZ 342 500 00) Konto 525 3299

Ihre Nachricht vom Mein Zeichen 42655 Solingen
O/St. 06.12.11

analysis and hardness measurement of two instruments (A.-Nr.5075)

*he OES-analysis (optical emission sprectroscopy)**

sample	AC 100/14 Metzenbaum scissors GER.ST/ST 14.5 cm	KD 240/16 Doyen intestinal clamp straight 16.0 cm
C	0,34	0,21
Si	0,38	0,37
Mn	0,37	0,53
P	0,029	0,014
S	0,024	0,016
Cr	13,56	14,01
Ni	0,21	0,08
Mo	0,06	0,01
Al	0,005	0,007
Cu	0,14	0,01
Co	0,03	0,03
Ti	0,004	0,006
eel-grade	~ AISI 420	~ AISI 420
hardness in HV10 ~ HRC**	529 – 542 ~ 51,0 – 51,8	434 – 437 ~ 44,0 – 44,2

*result given in wt.-%; ** measured in the cross-section

result: The material composition, tested by an OES-analysis of the instruments corresponds to the American stainless steel grade AISI 420.
The hardness of the scissors was tested with 529 – 542 HV10 (~ 51,0 – 51,8 HRC). The clamp was measured with 434 – 437 HV10 (~ 44,0 – 44,2 HRC). Both fulfil the requirement of the standard.

Oliver Stoß

Material analysis of Metzenbaum scissors and Doyen clamps.

PRODUCTION PROCESS

the nopa philosophy
PRODUCTION
Quality Plus

Purchase and control of forgings

v

Check forgings and raw material

v

Drilling and milling

v

Adapting and connecting parts

v

Hardening and tempering

v

Check hardness

v

Grinding and polishing

v

Cleaning

v

Marking LOT number

v

Final inspection

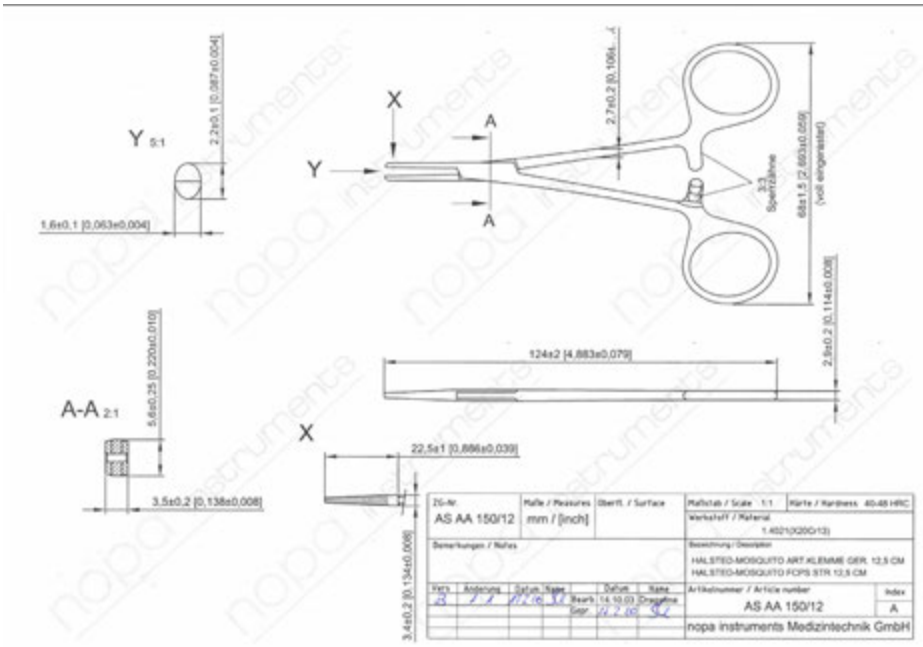
v

Check OK

v

Storage of the tested instruments

Technical drawing



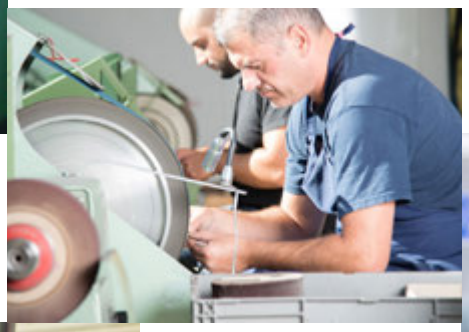
"From raw materials to the finished instrument"

Career history of a surgical forceps

PRINTS FROM OUR TESTING CENTRE

Testing of carbide inserts
in needle holders

Surface treatment



Cleaning and passivating of instruments

Hardness testing

sample of forgings, finished instruments
or drawings for the identification and testing
of the instruments

PA 04 – Scissors

nopa instruments

1.0 Description of the test method

1.1 Samples are taken according to **AA-02**.
1.2 Fundamental way to handle scissors:
- A pair of scissors may never be opened abruptly to the extent that the back of the blade hits the shank, thereby creating dents.
- When cutting, lateral pressure must never be applied. The scissor blades could otherwise be damaged.
- There must never be residue of grinding and polishing dust on the cutting blade. This could damage the blade.

1.3 Scissors identification:
- Compare the shape of the scissors using models and catalog material with regard to model and curvature.
- Check of total length using the catalog or a model
  Test equipment: calipers, ruler
- Check of the lot according to the instructions on the inspection plan
- Check of cutting angle according to attachment 2

Tolerance for the dimension of the total length of an instrument lot: +/- 5 mm

Scissors, which differentiate from each other too greatly in total length within one lot, are to be sorted out and rejected!
- In order to guarantee the exchangeability of every instrument of an article, the shape, curvature, surface finish, thickness, break of edges, blade and blade thickness must be identical.

1.4 Visual inspection:
- There must be no visible stains on the scissors (e.g. water spots, rust film, discoloration).
- The end of the screw (end of thread) must not be visible, i.e. the back side of the scissors must be planar. The end of the screw must never project out of the scissors (sharp, danger of injury).
- The surfaces must be free of pores, cracks, grooves, cinder residue, acidic fats and residue of grinding and polishing agents.
- The bolt head must be plane or semicircular, depending on the model.
- The slit of the screw must be straight and clean (no damage, e.g. from a screwdriver when screwing in a screw).
- Right and left part of the scissors must be uniform and match each other optically.
- Rings must be oval and perfectly polished, i.e. the raw material must have been uniformly removed.
- Edges in the joint must be broken roundly toward the shanks.
- The break of edges at the joint for scissors up to 12 cm long must be broken at least 0.2 and 0.3 mm and, for scissors of 13 cm length and longer, at least 0.5 mm, to avoid injuries.
- The screw joint must close completely, i.e. there must not be any large spaces or fringes visible when the scissors are looked at from the side.
- When the scissors are closed, no spaces must be visible between the shanks; the shanks must be parallel and superimposable, even when looked at from the side.
- The counterbore for the screw head must not be too large; i.e the gap between the diameter of the counterbore and the screw head diameter must not be large.
- When the scissors are open, there must not be a lot of play in the screw joint.
- No numbers may be punched into the shanks.

File name	Revision	written on	by	last changed on	by	Page
PA 04 – Scissors	A	18.10.04	SK	25.04.2014	SK	1 / 13

Example of one of the nopa internal test instructions in accordance with the standards.

PA 04 – Scissors

nopa instruments

1.5 Function test:
- The main function of a pair of scissors is its cutting capability and must be tested (Cutting capability test, see 5.6.1).
- When the scissors are closed, there must be no sharp edges/corners on them.
- In the case of dull scissors, the points at the end of the blades must be rounded.
- In the case of sharp scissors, the points must be symmetric and sharp.
- Scissors must operate well and may only close over the back third of the cutting blade. After this, the scissors must resist; i.e. the front 2/3 put up a low resistance, which brings about the cutting capability.
- The cutting surface must be fine and planar, i.e. it may not have any grooves, nicks or dents.
- No manufacturing residues, such as polishing dust or sand-blasting particles may be on the scissor blade or joint.
- The scissors may not hook during cutting, and no nicks may form on the cutting edge.
- A pair of scissors may not break or bend if used / handled properly.

1.6 Cutting capability test:
The cutting capability of the scissors is tested with a cutting test.

Cutting test procedure:
According to DIN 58298 Part 2, test material is to be used according to Table 2. **(see attachment)**

The scissors are to be cleaned before testing.
To test the cutting capability, 3 uninterrupted cuts over 2/3 of the cutting length of the scissors is cut through the test material, without applying lateral pressure. The test material must be smoothly cut, without tearing.
The test material is to be layered according to Table 2, according to the respective type of scissors.

The tip of the scissors must be checked with Latex, must not get caught.

1.7 Evaluation criteria:
1. If the scissors of the first random test are okay, the untested instruments are packaged in bundles of 10 in boxes.
2. Small optical defects, such as scratches, kinks, small dents, water spots, discoloration, etc. do not justify a return.
3. Optical defects, which can't be reworked in the workshop, justify a return.
4. Functional errors justify a return.

1.8 If the number of faulty instruments should be higher than the acceptance number defined in **AA-02**, the manager of Purchasing / Logistics or the QMB is to be informed. They decide whether a 100% test, special release or rejection of the lot is carried out.

the nopa philosophy
TESTING
Quality Plus

Our test procedures include, among others:

Model consistency test

Our instruments are checked on the basis of our master samples and the associated technical drawing.

Hardness test

Just as important as the right choice of raw material is a correct heat treatment during the production process, since the molecular structure and the associated hardness determine, among other things, the **durability and functionality** of the surgical instruments. The hardness of the instrument is tested according to DIN EN ISO 6507-1 or DIN ISO 3738-1.

Visual inspection

We distinguish between two types of visual inspection. On the one hand, this is performed by the trained eye of our qualified testing and quality assurance personnel and, on the other hand, optics are used with an up to 38-times magnification or microscope. We are thus able to determine all kinds of **defects from surface damage** down to the **smallest cracks** or **corrosion**.

Boiling test/autoclaving

After the usual **process guided cleaning**, the instruments are placed into a tank with demineralised water, which is then brought to a boil. A boiling test is deemed to have been passed when the instrument s**hows no signs of corrosion** after drying. As a further test, the instruments are subjected to a sterilization cycle. In an autoclave with steam and pressurised atmosphere, the instrument undergoes a sterilization cycle. The instruments **must not show any signs of corrosion** after this test either.

Function Test

Function is the priority here: the movement of working parts, locks, and the elasticity are tested. Cutting is checked using scissors, scalpels, and forceps and punches. All these and other functions are performed in accordance with the standard DIN 58298:2010-09.

Passivation

After the **complete cleaning** of the instruments, they are inserted into a special passivation liquid and passivated, in accordance with a specific process determined by the nature of the instrument, for between 5 to 30 minutes in an ultrasonic bath and then rinsed.

Marking

As we also offer, in addition to electro-chemical labelling, the possibility of laser labelling, it is an absolute must for us to test the labelling for **legibility, completeness, and cleanliness**. Our instruments only leave our facilities with a standardised and professional labelling.

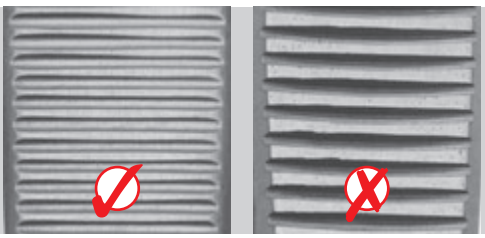
The basis of our quality controls are the **DIN standards for medical instruments** and the **Medical devices directive (93/42/EEC)**. These guidelines and legal foundations have been firmly rooted in all areas of our company for many years.

We have also created our own specific **nopa** test instructions for all our product groups. They define requirements on our products, services and company processes, and provide clarity on their characteristics.

Grip surfaces on a pair of tweezers

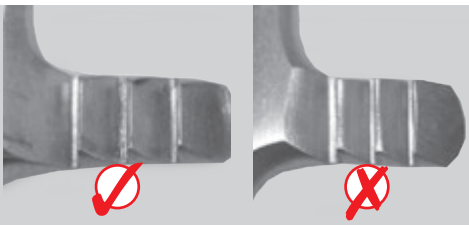
It is important that no sharp edges are present on the grip surfaces of a pair of tweezers.

A proper processing of the grip surfaces is essential.



Ratches

A ratched must be precisely milled to allow safe working conditions.

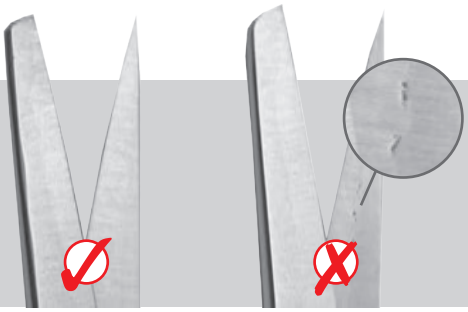


nopa instruments checks each instrument so that it meets our quality standards. Negligent processed instruments, compounds with pores or blunt instruments do not pass our strict quality controls.

Carbide scissors

Pores in the welding of a scissor blade of a pair of tungsten carbide scissors can lead to corrosion and breakage.

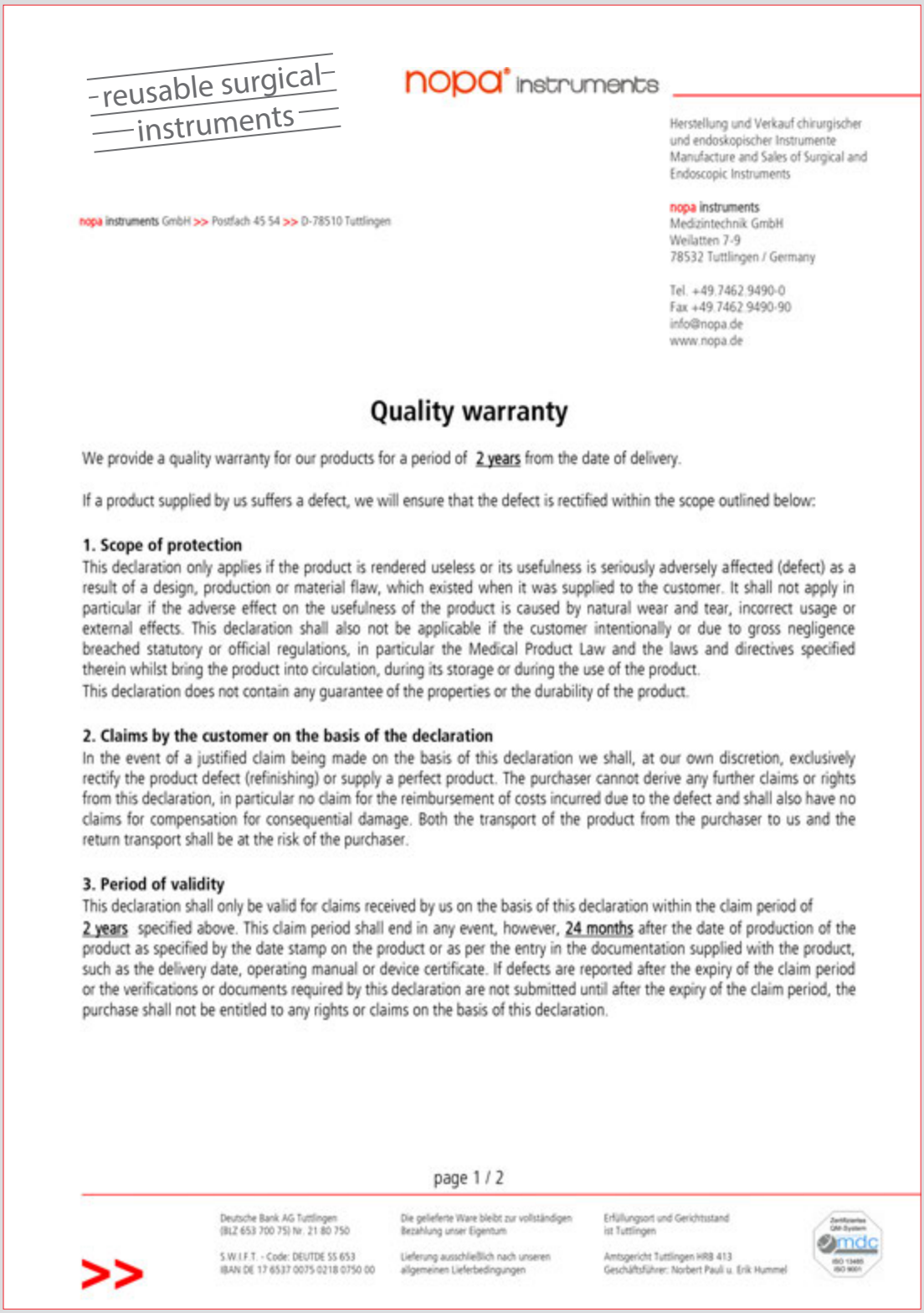
nopa TUC



Working ends of tweezers with groove

To ensure a secure grasp of the tweezers these must be precisely machined and free from burrs.

nopa guarantees high product quality.
The warranty period can, of course, be extended.



reusable surgical instruments

nopa instruments

Herstellung und Verkauf chirurgischer und endoskopischer Instrumente
Manufacture and Sales of Surgical and Endoscopic Instruments

nopa instruments GmbH >> Postfach 45 54 >> D-78510 Tuttlingen

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78532 Tuttlingen / Germany

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Quality warranty

We provide a quality warranty for our products for a period of 2 years from the date of delivery.

If a product supplied by us suffers a defect, we will ensure that the defect is rectified within the scope outlined below:

1. Scope of protection
This declaration only applies if the product is rendered useless or its usefulness is seriously adversely affected (defect) as a result of a design, production or material flaw, which existed when it was supplied to the customer. It shall not apply in particular if the adverse effect on the usefulness of the product is caused by natural wear and tear, incorrect usage or external effects. This declaration shall also not be applicable if the customer intentionally or due to gross negligence breached statutory or official regulations, in particular the Medical Product Law and the laws and directives specified therein whilst bring the product into circulation, during its storage or during the use of the product.
This declaration does not contain any guarantee of the properties or the durability of the product.

2. Claims by the customer on the basis of the declaration
In the event of a justified claim being made on the basis of this declaration we shall, at our own discretion, exclusively rectify the product defect (refinishing) or supply a perfect product. The purchaser cannot derive any further claims or rights from this declaration, in particular no claim for the reimbursement of costs incurred due to the defect and shall also have no claims for compensation for consequential damage. Both the transport of the product from the purchaser to us and the return transport shall be at the risk of the purchaser.

3. Period of validity
This declaration shall only be valid for claims received by us on the basis of this declaration within the claim period of 2 years specified above. This claim period shall end in any event, however, 24 months after the date of production of the product as specified by the date stamp on the product or as per the entry in the documentation supplied with the product, such as the delivery date, operating manual or device certificate. If defects are reported after the expiry of the claim period or the verifications or documents required by this declaration are not submitted until after the expiry of the claim period, the purchase shall not be entitled to any rights or claims on the basis of this declaration.

page 1 / 2

Deutsche Bank AG Tuttlingen
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Die gelieferte Ware bleibt zur vollständigen Bezahlung unser Eigentum

Lieferung ausschließlich nach unseren allgemeinen Lieferbedingungen

Erfüllungsort und Gerichtsstand ist Tuttlingen

Amtsgericht Tuttlingen HRB 413
Geschäftsführer: Norbert Pauli u. Erik Hummel

nopa instruments

Herstellung und Verkauf chirurgischer
und endoskopischer Instrumente
Manufacture and Sales of Surgical and
Endoscopic Instruments

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nopa instruments GmbH >> Postfach 45 54 >> D-78510 Tuttlingen

4. Defect notification

As soon as the purchaser discovers a defect on the product, he must notify us of it in writing immediately but at the latest three working days after the discovery of the defect. Otherwise he will lose all claims on the basis of this declaration.

5. Making claims on the basis of the declaration

To make claims on the basis of this declaration, the following must be submitted or notified to us at the expense and risk of the customer:

- Detailed description of the defect,
- The date of production,
- The invoice, delivery note or other suitable documents to verify the date of production and the date of purchase from us.

6. Statute of limitations

If we do not acknowledge properly lodged claims based on this declaration in writing, all claims from this declaration shall become statue-barred six months after the date of the claim, but not before the end of the claim period.

7. Applicable law

Material German law shall apply exclusively to this declaration and all claims, rights and obligations resulting from it, excluding the standards of International Private Law and also excluding UN-Convention on Contracts for the International Sale of Goods (CISG).

Date, Company

THIS IS A TRANSLATION OF THE ORIGINAL TEXT IN GERMAN AND IS THEREFORE NOT LEGALLY BINDING AT ANY TIME. THE GERMAN ORIGINAL TEXT ALONE IS LEGALLY BINDING.

Deutsche Bank AG Tuttlingen
(BLZ 653 700 75) Nr. 21 80 750

S.W.I.F.T. - Code: DEUTDE 55 653
IBAN DE 17 6537 0075 0218 0750 00

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Amtsgericht Tuttlingen HRB 413
Geschäftsführer: Norbert Pauli u. Erik Hummel

EXHIBITIONS AND CONGRESSES

nopa instruments uses every opportunity to get and stay in touch with its customers and prospective customers. For this reason, we regularly attend exhibitions and congresses around the world.

Medica 2015

These include, among others:

>> **MEDICA,** Düsseldorf
>> **Arab Health,** Dubai
>> **Africa Health**, South Africa
>> **Medic East Africa,** Kenya
>> **Medic West Africa,** Nigeria
>> **Hospitalar,** Sao Paulo
>> **Medical Fair,** South-East Asia
>> **Zdravookhraneniye,** Russia
>> **Exposanita**, Italy
>> **Belarus Medica**, Minsk

>>

Our customer service team is always pleased to be there for you. We speak several languages, including: Deutsch, English, Français, Español, Italiano and русский.

the nopa philosophy
WORLDWIDE
Quality Plus

We are also always happy to hear the suggestions of our customers. That is why we are particularly proud to receive positive feedback on our performance and our quality from various countries around the world.

... find more feedback from our customers on our homepage at www.nopa.de

INTERNATIONAL RESPONSE

India
"We purchased a laparoscopy set from your esteem organization, Nopa Germany in September 1998, since then, we are very much satisfied with the performance."

Egypt
"Thank you very much for your great assistance and additions you made to us. I appreciate doing such a great job in such a short and precious time."

Australia
"Wow, just installed the new containers and the first time I am seeing them and wanted to comment that they are quite impressive especially the Locking side and more attractive."

Italy
„Grazie nopa. Sei super brava. A presto. un caro saluto"

Paraguay
"buenos días: la prueba fue excelente pero estaba esperando tener la carta o la respuesta oficial. Solo dos pasaron la prueba de esterilización y nopa fue uno de ellos es lo que me comentan así que te estaré informando supuestamente hoy tendría novedades sobre eso. Saludos cordiales."

Singapore
"Wow..... your service level is really fantastic. Beyond words. You have just saved us!! Thank you so very much. Lots of hugs and kisses."

USA
"I am so very happy with the qualitiy of your products. So are my customer. I am very close to distributing a catalogue featuring the instruments along with pictures. I have many distributors across the country waiting for its release. My customer stresses good quality and I try to provide an ease with ordering. With this in mind, I want to stress the importance of the etching on the instruments. This is very important to us."

South Africa
"Vielen Dank. This looks like a good amount of items, I think we can ship those. By the way, we got the instruments and catalogues from you guys. It is beautiful!! The instruments seems very high quality and well worked off, we are very exited to do more business with you!!"

nopa® instruments

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Manufacture and sale of surgical and endoscopic instruments.