Abstract:
Tracer instruments (in vivo), test soils and test probes (in vitro) are needed to examine surface layers which might contain infective material. Disinfection efficacy with the reduction of colony forming units (CFU) must be distinguished from dynamics of cleaning where a minimum of any surface-covering material must be reached to avoid camouflaging hiding microorganisms. In vivo-testing of clinically used instruments is important to show the levels of cleanliness which still are acceptable for sterile processing. It can be done directly on the instrument with the advantage of precise local analysis on the individual instrument or in the eluate with the advantage that the instrument goes quickly back to the processing cycle. Here, more data can be achieved. In vitro-testing allows to evaluate the parameters of cleanability which are instrument design, surface properties of metal and/or composites, steps of the processing cycle, design and programming of the automated cleaning device, or the selected cleaning solutions which can be evaluated. Grading of visual cleanliness is a simple but still effective method for judgment of cleanliness after clinical operation and after automated cleaning (before sterilisation). But still proteinacious material might be hidden on outer or inner surfaces. A protein indicating system (test kit) must be developed as visual-tactile control alone is not sufficient for the often complex instruments in all disciplines of medicine, from arthroscopy to traumatology. It may lead to a better quality control of the processing cycle as well as it helps to optimise medical devices involved.

In vivo-Testing of the Clinical Situation
Collecting clinical data on the surface of clinically used surgical instruments from all medical fields is necessary to know the quality and quantity of organic and inorganic material on outer and inner surfaces. Because there are different "sterile items" [Spaulding], tracer instruments were chosen from:
- Arthroscopy (meniscus forceps)
- Dentistry (drills)
- Endoscopy (biopsy forceps)
- Gynecology (specula)
- Liposcopy (suction, forceps, mono-, bipolar instruments)
- Traumatology/Ouropddary (bone drills)
- Surgery (scissors)

Meanwhile, we are performing a multicenter study in 6 central sterile supply units.

In vitro -Testing of Parameters of Cleanliness
The study design has to enable statistical analysis for the examined parameters which have to be correlated to clinical conditions. For economic reasons we are specializing on the SDS-OPA method where experiences are gained since more than 10 years in the field of food industries [Frister, Michels]. Parameters are:
- instrument design (structure and material of the surfaces, compounds and their connections)
- measurements on metal test plates to determine recovery rates
- measurements in the eluate taken from the instrument's surface allow to achieve clinically relevant data. The problem is, that there are many different instrument types and processing parameters.
- recovery rate then must be determined for any kind of analysis and for each step of testing (calibration, auto-probes).
- In vivo the source, quality and quantity of the organic debris remain partly hidden.
- Recovery rates can only be measured in vitro. They depend on the chosen test soil, surface and material properties, instrument design and the different parameters of processing.
- Native liked as test soil seems most adequate but is too precious for routine testing. Because of its complexity (liquid, particles, thrombogenic activity) it is difficult to find an adequate substitute.
- Quality control for the cleaning step needs a standardised test method (test kit). Especially, the choice of test soil must be defined and correlated to the clinical situation.

We thank W. Gather for photos and scanning, I. Cramer, M. Koschke, S. Kügler for their precise measurements.

How Clean are Sterile Instruments?
Parameters - Testing - Clinical Data
Th. Fengler, H. Pahlke, S. Bisson, W. Michels*, E. Kraas
Chirurgie-Instrumenten-Arbeitsgruppe (CIA) am Krankenhaus Moabit, Turmstr. 21, D - 10559 Berlin
* D - 33332 Gütersloh, GERMANY