PROCESSING INSTRUCTIONS DEXTER ENDOSCOPE ARM

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DEXTER ENDOSCOPE ARM is the trade name of the SOLOASSIST IID, which was developed within the SOLOASSIST II product family.

The DEXTER ENDOSCOPE ARM, or SOLOASSIST IID, is a customised product variant of the SOLOASSIST II.

1 Introduction

	Except for the CANTILEVER, the JOINT, the PROBE PIN, the TENSION SLEEVE and the ENDOSCOPE CLAMP - the DEXTER ENDOSCOPE ARM as well as the POWER SUPPLY are **not** suited for the mechanical/ automated cleaning or disinfection process!

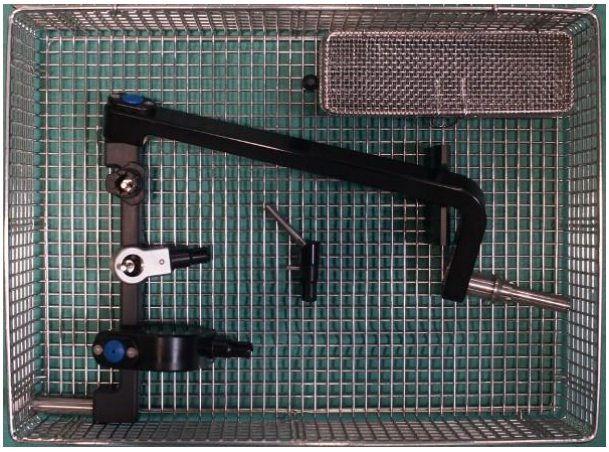


fig. 1: Fully equipped STERILISATION TRAY XL

The term **"STERILISABLE ARM COMPONENTS"** used in the following refers to the **CANTILEVER,** the **JOINT,** the **PROBE PIN**, the **ENDOSCOPE CLAMP** and the **TENSION SLEEVE**.

	Never put the STERILISABLE ARM COMPONENTS into a disinfection bath together with contaminated surgical instruments.
	After use, do not store the STERILISABLE ARM COMPONENTS together with contaminated surgical instruments in a container.

General basics:

The STERILISABLE ARM COMPONENTS must be cleaned, disinfected and sterilised prior to each use; this also applies in particular for the first time use after the delivery as all STERILISABLE ARM COMPONENTS are not delivered in a sterilised condition (clean and disinfect the components after the removal of the protective transport packaging; sterilise the components according to the corresponding packaging). An effective cleaning and disinfection is absolutely necessary for an effective sterilisation.

Within the scope of your responsibility, please ensure the sterility during use:

- by generally using only sufficiently device-specific and product-specific validated processes for the cleaning/disinfection and sterilisation,
- by inspecting and maintaining the devices (disinfector, steriliser) on a regular basis
- by adhering with the validated parameters with every cycle.

	Please additionally observe the legal regulations valid in your country as well as the hygiene regulations in your department. This applies especially to the various requirements in regard to an effective prion deactivation.
	If there is any suspicion that instruments have been contaminated with prions, we recommend disposing of these instruments and no longer using them!
	If the STERILISABLE ARM COMPONENTS have been treated with unsuitable detergents, disinfectants or rinse aids, or if you suspect that they contain incompatible chemicals, stop using the STERILISABLE ARM COMPONENTS and dispose of them!

2 Cleaning, disinfection and sterilisation

Basics:

You should preferably use a mechanised process (disinfector) for the cleaning and disinfection. A mere manual cleaning / disinfection process should be applied only if a mechanised process is not available and then only by following very carefully the manual cleaning / disinfection step as the effectiveness and reproducibility is significantly lower.

The pre-treatment is to be carried out in both cases.

	The use of a manual cleaning and disinfection process must be secured by an additional product- and process-specific validation in the responsibility of the user.

2.1 Pre-treatment

Rough contaminations on the STERILISABLE ARM COMPONENTS must be removed directly after use (within a maximum of 2 h).

Use running water or an disinfection solution; the disinfection solution should be free of aldehyde (otherwise fixation of blood contaminations), should have a proven effectiveness (e.g. VAH/DGHM FDA approvals or CE label), be suitable for the disinfection of the STERILISABLE ARM COMPONENTS and be compatible with them (see "Material resistance").

For the manual removal of contaminations, use only a soft brush or a clean soft cloth that you use for only this purpose. Never use metal brushes or steel wool.

Step	Description
	Detach the JOINT from the CANTILEVER by pressing the blue unlocking button (if it has not already been done).
	Detach the ENDOSCOPE CLAMP from the JOINT by pressing the blue unlocking button (if it has not already been done).
	Unscrew the TENSION SLEEVE from the ENDOSCOPE CLAMP (if it has not already been done).

Table 1: Pre-treatment

	Please note that the disinfection solution applied during the pre-treatment is only for the personal protection and that it is no substitute for the subsequent disinfection to be carried out – after the cleaning!

2.2 Mechanical cleaning and disinfection

(Disinfector)

When selecting the disinfectors, make sure

- that the disinfector's effectiveness has been tested (e.g. DGHM or FDA approval and/or CE label in accordance with DIN EN ISO 15883),
- that, if possible, a tested program for the thermal disinfection (A0 value > 3000 or – in case of older devices – at least 5 min at 90 °C) is used (in case of a chemical disinfection there is a risk of residues from the disinfection solutions on the CANTILEVER),
- that the program used is suitable for the STERILISABLE ARM COMPONENTS and that it has a sufficient number of rinse cycles,
- only low-germ (max. 10 germs/ml) water low in endotoxins (max. 0.25 endotoxin units/ml) (e.g. purified /highly purified water) is used for the flushing,
- that the air used for the drying is filtered and
- that the disinfector is maintained and inspected on a regular basis.

When selecting the cleaning agent system, make sure

- that it is generally suited for the cleaning of metal and plastic instruments,
- that - unless a thermal disinfection is applied - a suitable disinfection solution with a proven effectiveness (e.g. VAH/DGHM and/or FDA approval and/or CE label) is used in addition and that it is compatible with the cleaning agent used and
- that the chemicals used are compatible with the STERILISABLE ARM COMPONENTS (see "Material resistance").

	The concentrations provided by the manufacturer of the cleaning / disinfection solutions must be adhered to.

Procedure:

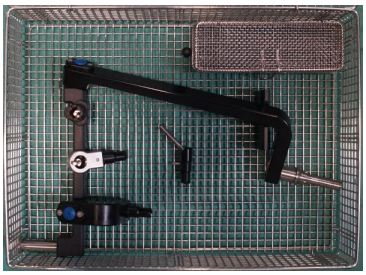
Step	Descritption
	Place the PROBE PIN into the STERILISATION TRAY XL. Attach the CANTILEVER, the JOINT, the ENDOSCOPE CLAMP and the TENSION SLEEVE to the rinse pipes of the STERILISATION TRAY XL as shown.
	Insert the prepared STERILISATION TRAY XL into the disinfector and connect the STERILISATION TRAY XL via the Luer-lock connection to the rinse supply of the disinfector. Start the program.

Table 2: Mechanical cleaning and disinfection

	Please ensure the correct position of the parts in the STERILISATION TRAY XL (as shown).

Remove the individual parts from the disinfector after the end of the program.

Inspect and package the STERILISABLE ARM COMPONENTS as soon as possible after the removal (see "Inspection" "Maintenance" and "Sterilisation", if necessary, at a clean location after an additional drying with filtered air).

The proof for the general suitability for an effective mechanical cleaning and disinfection has been provided by an independent accredited test lab using the disinfector G 7836 CD (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the alkaline cleaning agent Neodisher MediClean Forte (Dr. Weigert GmbH & Co. KG, Hamburg). The procedure described above has been used for this.

Check:

Check all individual parts after the cleaning or the cleaning/disinfection for corrosion, damaged surfaces, chippings and contaminations and separate the damaged individual parts (limited number of reuse, see "Reusability"). Individual parts still contaminated must be cleaned and disinfected again.

Maintenance:

Maintenance of the STERILISABLE ARM COMPONENTS is generally not required. An assembly of the individual STERILISABLE ARM COMPONENTS is not required.

Do not use instrument oil under any circumstances.

2.3 Steam pressure sterilisation (fractional vacuum process)

For the sterilisation, only a **steam pressure sterilisation using the fractional vacuum process** is permitted. All other sterilisation processes are not permitted.

	The gravity method is generally not permitted.
	The flash sterilisation method is generally not permitted.
	Also, do not use hot air sterilisation, radiation sterilisation, sterilisation using the low temperature plasma method (Sterrad; H202) as well as no formaldehyde or ethylenoxide sterilisation.

Packaging:

Step	Description
	Properly place the cleaned and disinfected STERILISABLE ARM COMPONENTS into the corresponding STERILISATION TRAY XL.

Table 3: Packaging

Please package the STERILISABLE ARM COMPONENTS and/or the fully loaded STERILISATION TRAY XL into suitable sterile barrier systems (sterilisation containers) that meet the following requirements:

- DIN EN ISO/ANSI AAMI ISO 11607
- suitable for steam pressure sterilisation (temperature resistance up to at least 138 °C (280°F), sufficient steam permeability)
- sufficient protection of the instruments or sterilisation packages against mechanical damage
- regular maintenance according to the specifications of the manufacturers (sterilisation container)

Steam sterilisation:

- fractional vacuum process
- Steam steriliser according to DIN EN 13060 or DIN EN 285
- validated according to DIN EN ISO17665 and ANSI AAMI ST79 (valid IQ/OQ (commissioning) and product-specific performance assessment (PQ))
- maximum sterilisation temperature 134 °C (273 °F; plus tolerance according to DIN EN ISO 17665 (previously: DIN EN 554/ANSI AAMI ISO 11134))
- Sterilisations time (exposure time at the sterilisation temperature) at least 5 min (or 18 min in case of a prion deactivation) at 132 °C (270 °F) / 134 °C (273 °F)

The proof for the general suitability of the STERILISABLE ARM COMPONENTS for an effective steam pressure sterilisation has been provided by an independent accredited test lab using the steam steriliser Zirbus 6x6x6 (Zirbus technology GmbH, Bad Grund) and the fractional vacuum process. The typical conditions in the clinic as well as the procedure described above have been used for this.

Storage:

Once sterilised, the STERILISABLE ARM COMPONENTS must be stored dry and dust-free in the sterile barrier system.

Material resistance:

Please note that the STERILISABLE ARM COMPONENTS are made of the plastic **PPSU** (polyphenylsulfone) and **stainless steel** (1.4301(=AISI 304) and 1.4305(=AISI 303)). Do not use any chemicals that could attack these materials during the entire reprocessing process!

When selecting the cleaning and disinfection solutions, please make sure that it does not include the following ingredients:

- Organic, mineral and oxidizing acids with a pH value < 5
- Bases with a pH value > 11
- Oxidation agents (e.g. hydrogen peroxides)
- Organic solvents (e.g. alcohol, ether, ketones, benzene)
- Halogens (chlorine, iodine, bromine)
- Aromatic/halogenated hydrocarbons

	If the STERILISABLE ARM COMPONENTS have been treated with unsuitable detergents, disinfectants or rinse aids, or if you suspect that they contain incompatible chemicals, stop using the STERILISABLE ARM COMPONENTS and dispose of them!
	We recommend the use of gentle neutral-enzymatic cleaning solutions or alkaline cleaning solutions (pH < 11) for the mechanical cleaning.

Never use metal brushes or steel wool to clean the STERILISABLE ARM COMPONENTS and the STERILISATION TRAY.

All STERILISABLE ARM COMPONENTS as well as the STERILISATION TRAY may not be exposed to temperatures higher than 138 °C (280 °F)!

Reusability:

CANTILEVER, JOINT, PROBE PIN and ENDOSCOPE CLAMP

These components can be – with the corresponding care and if they are not damaged and not contaminated – reused for at least 500 times; the user is responsible for any use beyond that number or the use of damaged and/or contaminated parts.

TENSION SLEEVE

This component can be – with the corresponding care and if they are not damaged and not contaminated – reused for at least 100 times; the user is responsible for any use beyond that number or the use of damaged and/or contaminated parts.

	The number of reprocessing cycles can be achieved by using the standardised sterilisation time of 5 minutes. In contrast, the application of a sterilisation time of 18 minutes (attempt at thermal prion inactivation) leads to accelerated ageing and premature destruction of the components.
	If there is any suspicion that instruments have been contaminated with prions, we recommend disposing of these instruments and no longer using them!

AKTORmed GmbH
Neugablonzer Str. 13
D-93073 Neutraubling

Internet: www.aktormed.com