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INSTRUCTIONS FOR REPROCESSING OF GENERAL SURGICAL INSTRUMENTS

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Section	Title		Description
1	Intended use and area of application		The devices may only be used for their intended use in medical specialties, by appropriately trained and qualified personnel. The devices are not intended for use on the central circulatory or nervous system. The attending physician or the user is responsible for the selection of the devices for specific applications or operative use, appropriate training and information, and sufficient experience for handling the devices.
2	Applicable SKUs	Dressing Pliers	9065081, 9065082, 9065083, 9065084, 9065085, 9065086, 9065088, 9065089, 9065090, 9085276, 9085278.
		Tissue Pliers	9085283, 9085295, 9085296, 9085299, 9085301, 9085304.
		Scissors - Tissue	9065105, 9065106, 9065107, 9065109, 9065110, 9065115, 9085200, 9085204, 9085218.
		Scissors - Suture	9085114, 9085116, 9085118.
		Scissors - Crown and Collar	9085340, 9085344, 9085346.
		Hemostats	9065126, 9065127, 9065128, 9065129.
		Rubber Dam Punch	9065132
		Needle Holders	9085151, 9085153, 9085159, 9085162, 9085163, 9085165, 9085167.
		Spreaders	9085430, 9085431.
		German Biopsy Punch Forceps	9086410, 9086420, 9086430, 9086440.
3	Precautionary measures and warnings	Attention!	Medical devices have been designed for human use only and must not be used for any other purpose. Improper handling and care as well as improper use can lead to premature wear of the devices.
		Treatment of brand new devices	Factory-new devices must have undergone the complete reprocessing process once before being used. Protective caps and protective nets for sharp-edged devices must be completely removed beforehand.
		Load	Overloading of the devices must be avoided. Overloading can lead to bending or breaking and thus to the loss of functionality of the devices.
		Functional impairment	The devices corrode and their function is impaired if they come into contact with aggressive substances. For this reason, it is essential to follow the reprocessing and sterilization instructions.
		Operating conditions	To ensure the safe operation of the aforementioned devices, correct maintenance and care of the devices is essential. In addition, a functional or visual check should be carried out before each use. For this reason, we refer to the relevant sections in these reprocessing instructions.
		Reprocess-ability	For the reprocessing of devices where TSE/CJD contamination is to be feared, the guidelines of the World Health Organization (WHO), as well as the national requirements for hospital hygiene, must be followed. The safest and clearest way to ensure that there is no risk of residual infectivity from contaminated products and other materials is to dispose of them by incineration. In certain public health situations, a less effective method may be preferred, in compliance with national requirements. The steam sterilization parameters recommended by WHO for prion inactivation, but with limited effectiveness, are: 134°C/273°F for 18 minutes.
		Storage	There are no specific requirements for storing the devices before sterilization. Nevertheless, we recommend storing the medical devices in a clean and dry environment.
4	Liability and warranty		The devices may only be used for their intended purpose in the medical fields by appropriately trained and qualified personnel. The attending physician or the user is responsible for the selection of the devices for specific applications or operative use, for appropriate training and information, and for sufficient experience in handling the devices. The manufacturer does not take responsibility for damage resulting from repair or maintenance by unauthorized parties.
5	Obligation to report		All serious incidents related to the devices must be reported to the manufacturer and the competent authority of the member state where the user and/or patient is established.
6	Sterility: Delivery condition		The medical devices are delivered in a non-sterile state and must be processed and sterilized by the user in accordance with the following instructions before the first and each subsequent use.

Premier® Dental Products Company
1710 Romano Drive, Plymouth Meeting, PA 19462, USA
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7	Limitation of reprocessing, disposal		Frequent reprocessing has little effect on the devices. Product life is limited by wear due to intended use and damage to the device. The device may no longer be used, among others, under the following aspects: Corrosion, damage, fractures, cracks, deformation, porosity, functional limitations, devices with unrecognizable or missing labeling. Therefore, the corresponding instructions for functional testing by the reprocessor must be implemented. Please dispose of the devices properly or to a recycling system at the end of the product life. The national regulations and disposal guidelines must be observed!
8	Processing		See the following points
9	Warning notices		Tab water to be used must be of drinking water quality. If the device is not a one-piece device, the device must be disassembled as far as possible.
10	Place of use		Coarse soiling, residues of e.g. hemostatic agents, skin disinfectants and lubricants as well as corrosive drugs should, if possible, be removed before discarding the device. Any contamination must be rinsed or wiped off immediately after use. The device should not be cleaned with physiological saline solution or stored before dry disposal. Wherever possible, dry disposal should be preferred, as prolonged exposure of medical devices to solutions during wet disposal can lead to material damage (e.g. corrosion). Long waiting times before reprocessing, e.g. overnight or over the week-end, should be avoided (< 6 hours drying time after contamination).
11	Transport		The device is discarded after use without disinfectant or other additional liquids and transported to the reprocessing unit for medical devices. The device must be disposed of dry immediately after use. This means that the device must be transported in a closed container from the place of use to reprocessing without being placed in disinfectant solution or other liquids, so that no drying occurs on the device.
12	Pre-treatment		If the device is not a one-piece device, it must be disassembled as far as possible. • The device must be soaked in tab water (according to drinking water regulations) for 10 minutes while avoiding bubble formation on the surface of the device. • Rinse the device under cold tab water of drinking water quality (< 40° C) until all visible dirt has been removed. • Stubborn dirt must be removed with a soft brush. • Moving parts on the device must be moved back and forth at least ten times. • By means of a water pressure gun, - cracks - holes - edges must be rinsed intensively > 60 sec. with cold water (drinking water quality, < 40° C). For devices with lumen: • Additionally, fill the lumen with tab water (drinking water quality, < 40° C) using a disposable syringe (50 ml). The soaking time is 10 minutes. • Treat the lumens with a brush whose diameter and length are slightly larger than the diameter and length of the lumens. Brush through the lumens at least three times with the brush. • If cleaning with a brush is not feasible due to the small lumen diameters, the lumens must be flushed three times with a 50 ml disposable syringe. Use tab water (drinking water quality, < 40° C).
13	a) Manual Cleaning/ Disinfection/ Drying	Note:	Before ultrasonic cleaning, a pretreatment (see section 110) must be performed.
		Ultrasonic cleaning	• Immerse the devices in an ultrasonic bath (< 40° C) with a mildly alkaline detergent and a frequency of approx. 35 kHz. Sonication time must correspond to the detergent manufacturer's specifications. • A detergent suitable for ultrasonic cleaning must be used. The instructions of the manufacturer of the detergent must be followed. • Devices must be placed in such a way, that all surfaces are covered. • The devices must not touch each other. • Rinse the devices thoroughly (at least 1 min.) three times under cold water (drinking water quality, < 40° C).

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Section	Title	Description
14	Manual cleaning	Moving parts on the device must be moved back and forth at least ten times. The product is to be forwarded to the further processing steps in the opened state. For devices with lumen: • Treat the lumens with a brush whose diameter and length are slightly larger than the diameter and length of the lumens. Brush through the lumens at least three times with the brush. • If cleaning with a brush is not feasible due to the small lumen diameters, the lumens must be flushed three times with a 50 ml disposable syringe. Use tab water (drinking water quality, < 40° C). Use a mildly alkaline detergent and prepare the cleaning solution according to the manufacturer's instructions. Immerse the devices completely in the cleaning solution. Carry out all further cleaning steps below the liquid level to avoid splashing of contaminated liquid. The total exposure time in the cleaning solution must be in accordance with the manufacturer's instructions for the cleaning agent used. • Brush the devices completely in the solution with a soft brush for at least 1 minute. • Remove the devices from the cleaning solution and rinse it with water for at least 1 minute to completely remove the cleaning solution. • Using a water pressure gun (or similar) (>30 sec.) to rinse: - cracks - holes - edges using cold tab water (< 40° C, drinking water quality).
15	Manual disinfection	The specific instructions of the manufacturer and the disinfectants must be observed. Only disinfectants suitable for disinfection of medical devices may be used. • The devices must be completely immersed in disinfectants so that all surfaces are covered. The exposure time must be followed, as indicated by the manufacturer of the disinfectant. • The devices must not touch each other. • Moving parts on the device must be moved back and forth at least ten times. **Procedure after disinfection:** • Rinsing the devices in deionised water > 15 sec. • Moving parts on the device must be moved back and forth at least ten times while rinsing with deionised water. • The lumens must additionally be flushed with deionised water using a disposable syringe (50 ml) at least three times.
16	Manual drying	Dry manually with a lint-free disposable cloth until all surfaces are dry. The lumens must be ventilated using sterile and oil-free compressed air.
17	Note:	Pre-treatment (see section 110) must be carried out before mechanical cleaning.

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	b) Mechanical Cleaning/Disinfection/Drying	**Ultrasonic cleaning**	• Immerse the devices in an ultrasonic bath (< 40° C) with a mildly alkaline detergent and a frequency of approx. 35 kHz. Sonication time must correspond to the detergent manufacturer's specifications. • A detergent suitable for ultrasonic cleaning must be used. The instructions of the manufacturer of the detergent must be followed. • Devices must be placed in such a way, that all surfaces are covered. • The devices must not touch each other. • Rinse the devices thoroughly (at least 1 min.) three times under cold water (drinking water quality, < 40° C). • Procedure after ultrasound treatment: Rinse again using a water pressure gun (> 30 sec.) with cold tab water (< 40° C): - cracks - holes - edges • Treat the lumens with a brush whose diameter and length are slightly larger than the diameter and length of the lumens. Brush through the lumens at least three times with the brush. • If cleaning with a brush is not feasible due to the small lumen diameters, the lumens must be flushed three times with a 50 ml disposable syringe. Use tab water (drinking water quality, < 40° C). Moving parts on the device must be moved back and forth at least ten times while applying the water pressure gun.
18		**Preparation for decontamination**	The product is to be forwarded to the further processing steps in the opened state, if necessary with the help of an apparatus. If present, the handle spring must be unhooked. Rinse shadows must be avoided. The devices must be prepared in suitable strainer baskets or rinsing trays (select size to suit the devices). The devices should be placed with a minimum distance to other devices in the cleaning basket. Overlapping must be avoided in order to exclude damage to the devices during the cleaning process. The quantity and type of load in the product trays selected for cleaning must be carried out in such a way that no impairment of the cleaning result is to be expected. For devices with lumen: The device shall be positioned so that the water can flow into and out of the lumens.
19		**Automatic cleaning process**	(washing machine, WD according to EN ISO 15883): If a rinsing connection is available, the device must be connected to the designated fitting. • Pre-rinse for 5 minutes with cold tab water (drinking water quality) < 40° C. • Water drainage • 10 minutes cleaning with deionised water of 55° C with mild alkaline detergent • Water drainage • 1 minute rinse with deionised water • Water drainage • 1 minute rinse with deionised water • Water drainage The special instructions of the manufacturer of the cleaning machine and the cleaning agents must be observed. Use a cleaning agent that is suitable for a washer-disinfector.
20		**Automated disinfection**	Automatic thermal disinfection in washer-disinfectors, taking into account the national requirements for the A0 value; e.g. A0- value 3000: • 5 minutes disinfection with deionised water 90° C • Water drainage
21		**Automated drying**	Automatic drying according to the automatic drying process of the washer-disinfector for at least 15 minutes (at 90° C in the rinsing room). If necessary, subsequent manual drying with a lint-free cloth if wetness can be detected on the device.

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22	Inspections		The devices must be macroscopically clean after each cleaning, i.e. free of visible dirt. A stained device (corrosion, discoloration) must be sorted out immediately and subjected to special treatment. A contaminated device must be reprocessed. In the event of errors or damage, the device must be sorted out immediately. The following components must be checked with particular attention: - Notches - Blades - Points - Joints - Handle spring
23	Care of the devices		Allow the device to cool to room temperature. If the device has been disassembled, it must be reassembled before maintenance. Maintenance means applying instrument oil. Products with a joint or end (scissors, clamps, etc.) or with metallic sliding surfaces (ribbed scissors, punches, etc.) must be treated with steam sterilizable care products based on parafin /white oil. The oil must be suitable for the use with biomedical products and be physiologically safe. The care products prevent metal-on-metal friction and keep the products in good condition. Laser-marked products may fade when treated with basic cleaners containing phosphoric and hydrofluoric acids. As a result, the coding function may be impaired or lost. In general, surgical products must be subjected to permanent care before functional testing. Care products must act in such a way that even with their permanent use, sticking of the joint parts due to an additive effect is excluded.
24	Packaging		If not yet done, the disassembled device must be reassembled. The device is placed in a suitable, standard-compliant packaging for the respective device or in sterilization trays for sterilization in accordance with DIN EN ISO 11607 or DIN EN 868 and sealed. The packaging must meet the following requirements: • Suitable for steam sterilization (temperature resistance up to at least 138° C (280° F) sufficient vapor permeability). • Sufficient protection of devices or sterilization packaging against mechanical damage. • Regular maintenance according to the manufacturer's specifications (sterilization containers). • A maximum weight of 10 kg per package/contents of the sterilization container must not be exceeded.
25	Sterilization		Sterilization of the devices using the fractionated pre-vacuum method (according to DIN EN ISO 17665-1) taking into account the respective national requirements. The devices must be sterilized in suitable sterilization packaging. Sterilization must be carried out using a fractionated pre-vacuum process with three pre-vacuum cycles and drying in a vacuum for at least 10 minutes. The following parameters must be taken into account: | | Temperature | Time | | Europe | 134° C (273° F) | > 3 Min. | | USA | 132° C (270° F) | > 4 Min. | The autoclave manufacturer's instructions for use and the recommended guidelines for the maximum load of sterilization material must be observed. The autoclave must be installed, maintained, validated and calibrated according to regulations.
26	Additional Information		The reprocessor is responsible for ensuring that the reprocessing carried out with the equipment, materials and personnel used in the reprocessing facility achieves the desired results. This usually requires validation and routine monitoring of the process and equipment used.
27	Service, repair and return transport	Service and repair	Do not carry out any repairs or modifications to the devices yourself. This is the sole responsibility of the manufacturer's authorized personnel. Please contact us if you have any complaints, claims or information regarding our devices.
		Return transport	Defective or non-conforming devices must have gone through the entire reprocessing process before being returned for repair/service.

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Section	Title	Description
28	Storage and transport	• Protect against mechanical damage • Store dry and dust-free • Store and transport in safe containers/packaging • Handle, do not throw or drop with great care Appropriate approved sterilization packaging (e.g. according to DIN EN 868, ISO 11607) must be used for sterilization, subsequent transport and storage.
29	Inspection instruction	Before each use of the device, it must be checked for fractures, cracks, deformations, damage and functionality. Worn, corroded, deformed, porous or otherwise damaged devices must be sorted out. The following components must be checked with particular attention: - Notches - Blades - Points - Joints - Handle spring The stainless steels used for manufacturing of the devices form specific passive layers as protective layers due to their alloy. These steels show only limited resistance to the attack of chloride ions and aggressive media and liquids! In addition to the efforts made by the manufacturer in the selection of the right materials and in their careful processing, devices must be subjected to professional and continuous care and the correct preparation at the user's end.
30	Material resistance	When selecting cleaning agents and disinfectants, make sure that they do not contain the following ingredients: • Organic, mineral and oxidizing acids (minimum permissible pH value 5.5) • Alkalis/strong alkalis (neutral/enzymatic (max. permissible pH value 8.5, mandatory for devices made of aluminum or other alkali-sensitive materials) or alkaline cleaning agents (max. permissible pH value 11, mandatory for devices intended for use in prion-critical areas, e.g. in accordance with Appendix 7 of the KRINKO RKI BfArM recommendation for reprocessing)) • Organic solvents (e.g. alcohols, ethers, ketones, benzines) • Oxidizing agents (e.g. hydrogen peroxides) • Halogens (chlorine, iodine, bromine) • Aromatic/halogenated hydrocarbons

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