

Document name:			
iFIX Processing Instructions per ISO 17664			
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Author Release: Pedro Costa	Approver 1: Stephane Naudin	Approver 2:	Replaces: N/A

WARNINGS	Warning Do not use hydrogen peroxide or sodium hypochlorite (bleach) based cleaning agents, as they may degrade the iFIX Anchor Product materials and potentially result in patient injury Caution In case you want to use a different cleaning agent or you are unsure about its impact on the iFIX Anchor Product properties, please contact iSYS Medizintechnik GmbH or your local distributor.
Limitations on Reprocessing	Repeated processing has minimal effect on the performance iFIX Anchor Products up to 1000 cycles. End of life is achieved after 1000 uses and/or reprocessing cycles. It is recommended that users utilize a sprayable cleaning agent as wipes (dry or pre-moistened) may not achieve the same level of cleanliness

INSTRUCTIONS	
Point of Use	After using iFIX, remove all iFIX Fleece products and dispose them according with hospital regulations. Residue from the fleece may get caught in the iFIX Product Anchors. Remove the residual fleece using a lint roller. iFIX Anchor Products are cleaned after each patient exam.
Containment and transportation:	No particular requirements.
Preparation for Cleaning	No particular requirements. Disconnection of iFIX Anchor Products from the intervention or imaging table not required.
Automated Cleaning	Not allowed.
Manual Cleaning	Clean the iFIX Anchor Products using an alcoholic (e.g. 70% Isopropyl Alcohol, Incidin® Liquid or Mikrocid® AF Liquid) or quaternary-ammonium-based (e.g. Meliseptol® rapid) sprayable cleaning agent. Spray the iFIX Anchors with the cleaning agent until an even distribution of the cleaning agent is achieved and let dry. If disinfection is desired, make sure that the surface to be disinfected remains in contact with the disinfectant for the specified contact time as directed by the disinfectant manufacturer. - The contact time refers to the minimum amount of time the surface needs to remain visibly wet. - Spray additional times, if needed, to maintain continuous contact time with the disinfectant. Examine the surfaces for visible residues of soil. If soil is present, repeat cleaning.

Drying	Unless otherwise specified by the manufacturer of the cleaning agent: • 3min in case of quaternary ammonium-based cleaning agents. • 5min in case of alcohol-based cleaning agents.
Maintenance	No particular requirements.
Inspection Testing	Visual inspection only. Before next use, confirm the stability of the connection between the iFIX Fleece Product and the iFIX Anchor Product.
Packaging	No particular requirements.
Sterilization	Not allowed.
Storage	No particular requirements.

Additional information	No particular requirements.
Manufacturer contact	Contacting the manufacturer can be done through a local representative or distributor, or using the following manufacturer information: iSYS Medizintechnik GmbH, Bergwerksweg 21, 6370, Kitzbühel, Austria info@interventional-systems.com / +49 (8232) 99 41 956

The instructions provided above have been validated by iSYS Medizintechnik GmbH as being CAPABLE of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel in the processing facility achieve the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.



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iSYS Medizintechnik GmbH
Bergwerksweg 21
6370 Kitzbühel, Austria
Tel: +49 (8232) 99 41 956
info@interventional-systems.com