English EN

Richard Wolf Case and Tray Systems

PART LIST

Part Number	Description	UDI
8585.023	UNIVERSAL TRAY METAL reusable	00190776414429
8585.025	DEEP UNIVERSAL TRAY METAL reusable	00190776414436
8585.071	UNIVERSAL TRAY METAL reusable	00190776414450
8585.072	UNIVERSAL TRAY METAL reusable	00190776414467
8585.073	UNIVERSAL TRAY METAL reusable	00190776414474
8585.101	ENDOCAM TRAY METAL reusable	00190776414481
8585.145	UNIVERSAL TRAY METAL reusable	00190776414498
8585.911	SMALL COMPARTMENT F. METAL TRAY METAL reusable	00190776414504

INTENDED USE

- Richard Wolf case and tray systems are utilized to secure medical instruments during transport, storage and sterilization processing.

INTENDED USER PROFILE

- Hospital and surgical staff having adequate training and familiarity with the handling of instruments including but not limited to, the loading and unloading of, transport, storage, and sterilization of instruments in a case and tray system prior to and following surgical procedures.

INDICATIONS

- The Richard Wolf case and tray systems are intended for use in healthcare facilities to organize, enclose, sterilize, transport, and store medical devices and other instrumentation between surgical and other medical uses.
- The Richard Wolf case and tray systems are not intended on their own to maintain sterility; they are intended to be used in conjunction with a legally marketed, validated, FDA cleared sterilization wrap.
- Sterilization validation for the worst-case Richard Wolf case and tray system included surgical instruments such as rongeurs, forceps, wrenches, cutters, pliers, etc. The Richard Wolf case and tray system was validated with up to a 9.35 lb (4.24 kg) load of metal instruments and polymer handled instruments.

Sterilization Parameters:

Cycle Type	Temperature	Exposure Time	Pulses	Drying Time
Prevacuum	132°C (270°F)	4 minutes	3	40 minutes
Prevacuum	134°C (273°F)	3 minutes	3	45 minutes

DEVICE DESCRIPTION

- Richard Wolf case and tray systems are manufactured using stainless steel, anodized aluminum, nylon 11, and medical grade silicone materials.
- Case and tray systems are supplied NON-STERILE and must be inspected, cleaned and sterilized before use.
- Devices are not implantable.

WARNINGS

- Devices should be reprocessed as soon as possible following use. Instruments must be cleaned separately from cases and trays.
- If a device is/was used in a patient with, or suspected of having Creutzfeldt-Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of cross-contamination.

CAUTION

℞ Only

Federal U.S. Law restricts this device to sale, distribution, and use, by, or on order of a physician.

LIMITATIONS ON REPROCESSING

Repeated processing per this instruction for use has minimal effect on these devices. End of life is normally determined by wear and damage due to use.

DISCLAIMER

It is the responsibility of the reprocessor to ensure reprocessing is performed using equipment, materials and personnel in the reprocessing facility and achieves the desired result. This requires validation and

	routine monitoring of the process. Any deviation by the reprocessor from the instructions provided must be properly evaluated for effectiveness and potential adverse consequences.
MANUAL CLEANING	1. After each use, wash the case and tray system with a soft sponge and an aluminum safe, neutral pH detergent. A neutral pH detergent is required to avoid faded surface colors and deterioration of the anodized surface. 2. Thoroughly rinse the case and tray system with warm tap water for 1 minute and dry with a soft, absorbent cloth.
INSPECTION	• Visually inspect devices for damage or wear. • Do not use a case and tray system if the lid does not attach to the base securely or if the device is or appears damaged.
PACKAGING	• Only FDA cleared sterilization packaging materials should be used by the end user when packaging the devices. • To maintain sterility, the case and tray system must be wrapped in a standard, medical grade sterilization wrap using an approved double wrap method. • The end user should consult ANSI/AAMI ST79 or ISO 17665-1 for additional information on steam sterilization.
STERILIZATION	Sterilize with steam. The following are minimum cycles required for steam sterilization of the case and tray system when loaded with up to a 9.35 lb (4.24 kg) of metal instruments and polymer handled instruments: **Double Wrapped Case:** **Cycle Type** / **Temperature** / **Exposure Time** / **Pulses** / **Drying Time** Prevacuum / 132°C (270°F) / 4 minutes / 3 / 40 minutes Prevacuum / 134°C (273°F) / 3 minutes / 3 / 45 minutes **NOTE:** The case and tray systems have been validated at these parameters with a 9.35 lb (4.24 kg) load of metal instruments and polymer handled instruments. Deviations from this case loading or instrument type will require re-validation by the user. • Time and temperature parameters required for sterilization vary according to type of sterilizer, cycle design, and packaging material. It is critical that process parameters be validated for each facility's individual type of sterilization equipment and product load configuration. • Only steam sterilization cycles with the above listed parameters have been validated for use and have been shown to be compatible with the device design and specified instrument loading. A facility may choose to use different steam sterilization cycles other than the cycle suggested if the facility has properly validated the cycle to ensure adequate steam penetration and contact with the devices for sterilization. • Water droplets and visible signs of moisture on sterile packaging or the tape used to secure it, may compromise sterility of processed loads or be indicative of a sterilization process failure. Visually check outside wrapper for dryness. If there are water droplets or visible moisture on the exterior of the package or on the tape used to secure it, the pack or instrument tray is considered unacceptable. Repackage and re-sterilize case and tray systems with visible signs of moisture.
STORAGE	• After sterilization, case and tray systems should remain in sterilization packaging and be stored in a clean, dry cabinet or storage case. • Care should be taken when handling devices to avoid damaging the sterile barrier.
CONTACT	**Notice to Patient and User**: Any serious incident that has occurred in relation to the medical devices should be reported to the manufacturer.  **Manufactured by:** **Avalign Technologies, Inc.** 8727 Clinton Park Drive Fort Wayne, IN 46825 USA 1-877-289-1096 www.avalign.com product.questions@avalign.com  Richard Wolf Medical Instruments Corp. 353 Corporate Woods Parkway Vernon Hills, IL 60061 USA

Label Glossary

Symbol	Title	Symbol	Title
	Manufacturer and Date of Manufacture		Consult Instructions for Use
	Lot Number / Batch Code		Caution
	Catalogue Number		Federal Law (USA) restricts this device to sale by or on the order of a physician
	Medical Device		Distributor