DJO Surgical Instruments and Instrument Cases

Instrumente und Instrumentenbehälter von DJO Surgical

Instruments chirurgicaux et boîtiers à instruments DJO Surgical

Instrumentos y estuches de instrumentos quirúrgicos de DJO Surgical

Strumenti chirurgici e custodie DJO Surgical

Χειρουργικά όργανα και θήκες οργάνων DJO Surgical

DJO Surgical Aletleri ve Alet Kutuları

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djosurgical™

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The following instrument trays have been validated under the sterilization cycle outlined in this IFU:

FA XALT TRIAL (803-99-039)
FA FMP INSTRUMENT (803-99-018)

EN

Product Description

Recommendation for the Care and Handling for
DJO Surgical Instruments and Instrument Cases

REUSABLE INSTRUMENT DESCRIPTION	DJO Surgical instrumentation consists of devices and their accessories used in surgical procedures. Implantation of DJO Surgical products should only be performed with DJO Surgical instrumentation or instrumentation distributed by DJO Surgical.[1] DJO Surgical instruments and instrument cases are generally composed of titanium, stainless steel, aluminum, and/or polymeric materials. The cases may be multi-layered with various inserts to hold surgical instrumentation in place during handling and storage. The inserts may consist of trays, holders, and silicone mats. The instrument cases will allow sterilization of the contents to occur in a steam autoclave utilizing the cleaning, sterilization, and drying cycle that has been validated and detailed below. Instrument cases do not provide a sterile barrier and must be used in conjunction with sterilization wrap to maintain sterility. Instruments are provided non-sterile and should be stored in their original packaging until cleaned and sterilized according to the recommended guidelines listed below.
WARNINGS	Automated cleaning may not be thorough enough. Carefully inspect each instrument to ensure that all visible blood residue and other contaminants have been removed.
CAUTION	Federal Law (USA) restricts this device to sale by or on the order of a physician.
REPROCESSING LIMITATIONS	DJO Surgical instruments can be steam sterilized and repeat sterilization will not adversely affect them. If problems related to instrument sets are identified when using our instruments or instrument cases, please bring it to the attention of DJO Surgical for investigation. The lifetime of an instrument is typically limited by normal wear and damage due to use.
DISCLAIMER	DJO Surgical instrument cases are intended to protect instrumentation and facilitate the sterilization process by allowing steam penetration and drying. DJO Surgical has verified through laboratory testing that our instrument cases are suitable for the sterilization cycles listed in the sterilization section of the IFU. Health care personnel are ultimately responsible for ensuring that any packaging method or material, including a reusable rigid container system, is suitable for use in sterilization processing and sterility maintenance in their particular health care facility. Testing should be conducted in a health care facility to assure that conditions essential to sterilization can be achieved.

[1] For cleaning and sterilization of instrumentation distributed by DJO Surgical, please refer to the manufacturer's Instructions for Use provided in the Instrument Tray.

INSTRUCTIONS FOR USE

POINT OF USE PREPARATION	Keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments. The decontamination process should begin immediately after the completion of the surgical procedure. If cleaning must be delayed, place instruments in a covered container with appropriate enzymatic detergent to delay drying. Instruments should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.

	Wash all instruments whether or not they were used or were inadvertently contacted with blood. Disassemble instruments with removable parts; loosen instruments with movable parts, as applicable.
DISINFECTION	Saturate the surface completely with full strength disinfectant/cleaner* (e.g. CaviCide) and allow to remain in contact with devices for 5 minutes.
AUTOMATED CLEANING	DJO Surgical rigid instrument cases may be washed and/or disinfected by using an automated washer-disinfection unit utilizing thermal disinfection. Temperatures, cycles, and disinfectant type used should be as instructed by manufacturer of the washer-disinfection unit. For ultrasonic cleaning follow the manufacturer's specifications for suggested water level and concentration. When using mechanical washers, make sure the instruments are secured in place, and do not touch or overlap. Automated washer/disinfector systems are not recommended as the sole cleaning method for complex, surgical instruments. Complex instrumentation should be cleaned in accordance with the procedure described in the manual cleaning section.

MANUAL CLEANING	1. Pre-Cleaning: Remove gross contaminants by immersing the devices in room temperature neutral pH enzymatic cleaner* (e.g. MetriZyme) and disassemble/loosen instruments, if suitable. The majority of the surgical instruments and trial devices are simply constructed and will not require disassembly. However, some of the more complex instruments are made of several components and these should be disassembled into their individual parts prior to decontamination. Scrub with the appropriate soft bristle brush until visibly clean. 2. Washing: Immerse devices in the ultrasonic washer/cleaner with room temperature neutral pH enzymatic cleaner* (e.g. MetriZyme) and sonicate for 10 minutes. Ultrasonic cleaners can be used with hot water per the manufacturers' recommended temperature; however, room temperature was qualified. Be aware that loading patterns, water temperature, and other external factors may change the effectiveness of the equipment. 3. Rinsing: Thoroughly rinse the devices with deionized or distilled water. For example, a minimum of 2 minutes three (3) times. * Do not use high acidic (pH <4) or high alkaline (pH >10) products for disinfection or cleaning, since these can corrode metal, cause discoloration or stress fractures. DJO Surgical has qualified the above cleaning method with the provided solution examples, for a 3 Spore Log Reduction (SLR). Other cleaning/disinfection methods may also be suitable, however individuals or hospitals not using the recommended method are advised to validate any alternate method using appropriate laboratory techniques.
DRYING	Allow devices to air dry a minimum of 20 minutes prior to inspection and sterilization preparation. Instruments must be thoroughly dried to remove residual moisture before they are stored.
MAINTENANCE INSPECTION AND TESTING	After cleaning/disinfection, the disassembled instruments should be visually inspected. Check for misalignment, burrs, bent, or fractured tips. Mechanically test the working parts (e.g. hinges) to verify that each instrument functions throughout its intended range of motion. Place instruments into appropriate configuration within instrument case and wrap with protective sterilization wrap according to AAMI / AORN guidelines. Surgical instruments and instrument cases are susceptible to damage from prolonged use, and through misuse or rough handling. Care must be taken to avoid compromising their performance. To minimize damage, conduct the following: 1. Inspect instrument cases and instruments for damage when received and after each use and cleaning. Incompletely cleaned instruments should be re-cleaned, and those that need repair returned for servicing. 2. Only use an instrument for its intended purpose. 3. When handling sharp instruments use extreme caution to avoid injury. Consult with an infection control practitioner to develop safety procedures appropriate for all levels of direct instrument contact. 4. If instruments appear to be damaged in such a way that may compromise the performance of the instrument, contact your DJO Surgical representative for a replacement.
PACKAGING	Health care personnel are ultimately responsible for ensuring that any packaging method or material, including a reusable rigid container system, is suitable for use in sterilization processing and sterility maintenance in their particular health care facility.
TRANSPORT	Compliance with the general precautionary measures for handling contaminated/biologically hazardous materials is required.
STERILIZATION	Loaner instrument sets supplied by DJO Surgical have been thoroughly cleaned, inspected and tested for proper function prior to shipment. Unless otherwise indicated, these sets are NOT STERILE and must be sterilized prior to use. NOTE: DJO Surgical does not recommend Flash Sterilization within instrument cases or Chemical Sterilization. The following is a recommended minimum cycle for steam sterilization that has been validated by DJO Surgical under laboratory conditions to achieve a SAL of 10^{-6} with components loosened. DJO Surgical has data on file. Other sterilization cycles may also be suitable; however individuals or hospitals not using the recommended method are advised to validate any alternate method using appropriate laboratory techniques. Proper validation of the autoclave is essential to ensure proper sterilization temperatures and cycle times. Sterilization with a Pre-Vacuum Sterilizer (HI-VAC): 270° F (132° C), 4-minute exposure time, with 4 pulses and a 30-minute dry time. Sterilization with a Gravity Displacement Sterilizer: 270° F (132° C), 15-minute exposure time, with a 30-minute dry time.
STORAGE	Instruments must be thoroughly dried to remove residual moisture before they are stored. Instrument cases that have been processed and wrapped to maintain sterility should be stored in a manner to avoid extremes in temperature and moisture. Care must be taken in handling wrapped cases to prevent damage to the barrier. The health care facility should establish a shelf life for wrapped instrument cases, based upon the type of sterile wrap used and the recommendations of the sterile wrap manufacturer. The user must be aware that maintenance of sterility is event-related and that the probability of occurrence of a contaminating event increases over time and with handling.
CONTACT INFORMATION	DJO Surgical ATTN: Customer Service 9800 Metric Boulevard Austin TX, 78758 USA 1-800-456-8696

The instructions provided above have been validated by DJO Surgical as being capable of preparing a medical device for re-use. It remains the responsibility of the user to ensure that the reprocessing is performed using appropriate equipment and materials, and that personnel in the reprocessing facility have been adequately trained to achieve the desired result. This normally requires validation and routine monitoring of the process.

An electronic version of this IFU can be located at:
http://djoglobal.com/our-brands/djo-surgical

Some DJO Surgical products use SurgiBit® technology. The SurgiBit® technology is protected by the following patents: Drill Point protected under U.S. Design Patents D523313 & D523398. U.S. Utility Patents Pending.

	***Single use – do not reuse*** ***Zum einmaligen Gebrauch – Nicht zur Wiederverwendung*** ***Usage unique – Ne pas réutiliser*** ***Para un solo uso, no reutilizar*** ***Monouso – Non riutilizzare*** ***Για μία χρήση – μην επαναχρησιμοποιείτε*** ***Tek kullanımlıktır – tekrar kullanmayın***
	***Expiration Date*** ***Verwendbar bis*** ***Date de péremption*** ***Fecha de caducidad*** ***Data di scadenza*** ***Ημερομηνία λήξης*** ***Son Kullanma Tarihi***
	***Keep Dry*** ***Trocken aufbewahren*** ***Protéger de l'humidité*** ***Mantener seco*** ***Tenere all'asciutto*** ***Να διατηρείται στεγνό*** ***Kuru Muhafaza Edin***
	***Store in a cool place: Do not store in environments with the potential for extreme heat or direct sunlight*** ***Kühl lagern: Nicht in Umgebungen lagern, in denen starke Hitze oder direkte Sonneneinstrahlung möglich ist*** ***Conserver dans un endroit frais : Ne pas conserver dans un environnement potentiellement exposé à une chaleur extrême ou à la lumière solaire directe*** ***Almacenar en un lugar fresco: No almacenar en entornos en los que pueda haber calor extremo o exposición directa a la luz solar*** ***Conservare in un luogo fresco. Non conservare in ambienti soggetti a calore estremo o esposti alla luce solare diretta*** ***Να φυλάσσεται σε δροσερό χώρο: Να μη φυλάσσεται σε περιβάλλοντα με ενδεχόμενο παρουσίας υπερβολικής θερμότητας ή άμεσου ηλιακού φωτός*** ***Serin bir yerde saklayın: Aşırı sıcaklık veya doğrudan güneş ışığı alma olasılığı bulunan ortamlarda saklamayın***
LOT	***Lot number/Batch Code*** ***Chargennummer/Chargenbezeichnung*** ***Numéro de lot/Code de lot*** ***Número de lote/Código de lote*** ***Numero di lotto/Codice di partita*** ***Αριθμός/κωδικός παρτίδας*** ***Lot sayısı/Parti Kodu***
STERILE	***Sterile*** ***Steril*** ***Stérile*** ***Estéril*** ***Sterile*** ***Στείρο*** ***Steril***
STERILE R	***Sterility symbol: R: Sterile Using Irradiation*** ***Sterilitätssymbol: R: strahlensterilisiert*** ***Symbole de stérilité : R : Stérilisé par rayonnement*** ***Símbolo de esterilidad: R: Estéril utilizando irradiación*** ***Simbolo di sterilità: R: Sterilizzato mediante irrradiazione*** ***Σύμβολο στειρότητας: R: Στείρο με χρήση ακτινοβολίας*** ***Sterilite işareti: R: Radyasyonla Sterilize Edilmiştir***
STERILE H_2O_2	***Sterile symbol : H2O2: Sterilized Using Hydrogen Peroxide Gas Plasma*** ***Sterilitätssymbol: H2O2: Sterilisiert mit Wasserstoffperoxid-Gasplasma*** ***Symbole de stérilité : H2O2: stérilisé par plasma gazeux de peroxyde d'oxygène*** ***Símbolo de esterilidad: H2O2: Esterilizado con plasma de gas de peróxido de hidrógeno*** ***Simbolo di sterilità: H2O2: Sterilizzato al gas plasma di perossido di idrogeno*** ***Σύμβολο αποστείρωσης: H2O2: Έχει αποστειρωθεί με χρήση αερίου πλάσματος υπεροξειδίου του υδρογόνου***

	Steril sembolü: H2O2: Hidrojen Peroksit Gaz Plasma Kullanılarak Sterilize Edilmiştir
	***Non-sterile*** ***Nicht steril*** ***Non stérile*** ***No estéril*** ***Non sterile*** ***Μη στείρο*** ***Steril değildir***
	***See "Instructions for Use"*** ***Siehe „Gebrauchsanleitung"*** ***Consulter le mode d'emploi*** ***Consultar las instrucciones de uso*** ***Vedere le istruzioni per l'uso*** ***Δείτε τις «Οδηγίες χρήσης»*** ***Bkz. "Kullanma Talimatları"***
	***Manufacturer*** ***Hersteller*** ***Fabricant*** ***Fabricante*** ***Fabbricante*** ***Κατασκευαστής*** ***Üretici***
QTY	***Quantity of items in package*** ***Anzahl Artikel pro Packung*** ***Quantité d'articles dans l'emballage*** ***Cantidad de artículos en el envase*** ***Quantità di prodotti nella confezione*** ***Αριθμός τεμαχίων στη συσκευασία*** ***Paket içindeki ürün sayısı***
EC REP	***Authorized Representative in European Community*** ***Bevollmächtigter in der EU*** ***Mandataire dans la Communauté européenne*** ***Representante autorizado en la Unión Europea*** ***Rappresentante Autorizzato nella Comunità Europea*** ***Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα*** ***Avrupa Topluluğu Yetkili Temsilcisi***
REF	***Catalog Number*** ***Bestellnummer*** ***Numéro de référence*** ***Número de catálogo*** ***Numero di catalogo*** ***Αριθμός καταλόγου*** ***Katalog Numarası***
℞	***Federal Law (USA) restricts this device to sale by or on the order of a physician.*** ***Laut US-Gesetzgebung darf dieses Produkt nur von einem Arzt oder im Auftrag eines Arztes gekauft werden.*** ***Selon la loi fédérale (États-Unis), ce dispositif ne peut être vendu que par un médecin ou sur sa prescription.*** ***Las leyes federales estadounidenses restringen la venta de este dispositivo a médicos o por prescripción facultativa.*** ***Le leggi federali degli Stati Uniti d'America vietano la vendita del presente dispositivo a personale non autorizzato e/o senza prescrizione.*** ***Η ομοσπονδιακή νομοθεσία (των Η.Π.Α.) περιορίζει την πώληση της διάταξης αυτής σε ιατρούς ή κατόπιν εντολής ιατρού.*** ***ABD yasalarına göre bu cihaz sadece bir doktor tarafından veya emriyle satılabilir.***