

Sterilization and Hygiene DrillSaw Sports 400™ Power System

Preparation Guide



Information for Preparation

Description

The modular DrillSaw Sports 400™ battery-powered system from Arthrex is ideally suited for use in small bone surgery such as sports medicine and fracture management. The modular design ensures the highest flexibility for the user. The latest Li-ion battery technology guarantees a lightweight system with full power and maximum torque for all applications.

Hygienic Maintenance

	Allowed
Preparation: Remove the rotary instrument or saw, remove the adapter from the driver handpiece, and remove the battery pack	Yes
If heavily soiled, clean first with disinfectant cloths	Yes
We recommend wiping with surface disinfectants to clean	Yes
Arthrex products with official symbols can be cleaned and disinfected in a thermal washer disinfectant	Yes
Ultrasonic bath for driver handpiece, sterile casing, and adapters	No
Only use cleaning types that are certified by officially approved institutions	Yes
Thermal disinfection	Yes
Sterilization in accordance with EN 285/EN 13060, class B	Yes
Drying: Moisture on the battery contact points can lead to malfunctions!	Yes
Storage in a dust-free and dry environment	Yes
A function test during preparation is not necessary	-

System is delivered unsterile!

Hygiene Manual - General



Follow your country-specific guidelines, standards, and requirements for cleaning, disinfection, and sterilization. Always wear proper PPE (personal protective equipment) such as gloves, eye protection, face shields, gowns, etc.

To make cleaning and disinfecting easier, always clean and disinfect the DrillSaw Sports 400 system immediately after use; do not allow bodily fluids or tissue to dry on any of the system components.

The handpiece and attachments are supplied non-sterile. With the exception of the battery pack and charging unit, Arthrex recommends processing system components (handpieces, attachments, transfer plates, and battery housings) with a thermal washer disinfectant. Follow the manufacturer's recommendations for devices and cleaning agents for your facility's specific washer.

Remove any attachments and the battery housing from the handpiece.

Remove the battery from the battery housing, and disinfect the battery pack with noncorrosive disinfecting cleaners approved by your facility.

Remove any loose debris from system components by rinsing them in a disinfectant/water mix approved by your facility. Place the instruments into the washer so that all cannulated and recessed parts will drain accordingly during the wash cycle (in an upright position). Ensure that items such as the battery housing are open and point downward so that they do not retain water.



Using a noncorrosive cleaning agent approved by your facility and a stiff bristled brush, remove any gross debris from all surfaces of the handpiece and associated attachments. Be careful not to damage any of the battery contacts.

Do NOT autoclave the battery pack or put it through the washer.

If your washer has an ultrasonic cleaning stage, you must deactivate it prior to cleaning the DrillSaw Sports 400™ system.

Ultrasonic cleaning of the system is NOT approved and can cause damage to the handpiece.

Manual Pre-cleaning

Manual pre-cleaning prior to mechanical/automated cleaning/disinfection is important to ensure that cannulations and other areas that are difficult to access are clean.

1. Clean the instruments under running water using a soft bristled brush until all visible residues have been removed from the surface. For cannulations of the handpiece and attachments, a special cleaning brush should be used.
2. Manipulate all moving parts under running water.
3. After manual cleaning, inspect the cannulations, coupling sleeves, etc for visible residue.

Repeat the manual cleaning process if necessary.

Mechanical Cleaning, Disinfection, and Drying

A cycle for mechanical washing is provided below as an example.

- 5 minutes cold prewash at $20 \pm 5^{\circ}\text{C}$ ($68 \pm 9^{\circ}\text{F}$)
- 10 minutes cleaning wash (enzymatic or alkaline agent) at 65.5°C (150°F)
- 3 minutes neutralization (acidic cleaning detergents) at 50°C (122°F)
- 3 minutes rinse with demineralized water at 50°C (122°F)
- 5 minutes thermal rinse at 90°C (194°F)
- 40 minutes drying phase at a high temperature of 115°C (239°F)

Caution: Low-acid or high-alkaline solutions are not recommended as they corrode metal and anodized aluminum and can cause damage to polymer plastics.

Sterilization and Storage

Sterilization capabilities, cleaning, disinfecting, handling, and storage of instrumentation are the responsibility of the qualified facility and/or user personnel. Qualified personnel must properly clean and disinfect the instruments prior to sterilization.

After sterilization in the autoclave, let the accessory device cool slowly. **NEVER** force the cooling of the handpiece or accessories. This will damage the electronic components and seals.



Place all components in the instrument tray. While you may use filtered trays, it is recommended that you use an Arthrex-approved instrument tray such as AR-400WMC.

Use a sterilization wrap approved by your facility for packing and storing sterile goods according to EN 868-5. If you are using a filtered tray, please observe the manufacturer's recommendations for that tray.

Approved Sterilization

Follow your country-specific directives, standards, and guidelines.

Place the instrument tray in the sterilization unit and process according to the following minimum exposure and dry times. Steam sterilization class B (pre- and post-vacuum) with sterilizers in accordance with EN 13060.

Sterilization guidelines for the Drillsaw Sports 400™ handpiece, accessories, and attachments, individually or in the AR-400AC, AR-400AC-2, or AR-400WMC instrument tray, wrapped or unwrapped.

Sterilization Type	Minimum Temperature	Minimum Exposure Time	Dry Cycle
Steam vacuum	132°C (270°F)	4 minutes	30 minutes

*** Caution: To maintain the highest possible level of performance and reliability of handpieces and attachments, the dry cycle should be run in every sterilization cycle. Operating a handpiece or attachment that has not cooled and dried sufficiently may also decrease product reliability and/or performance.**

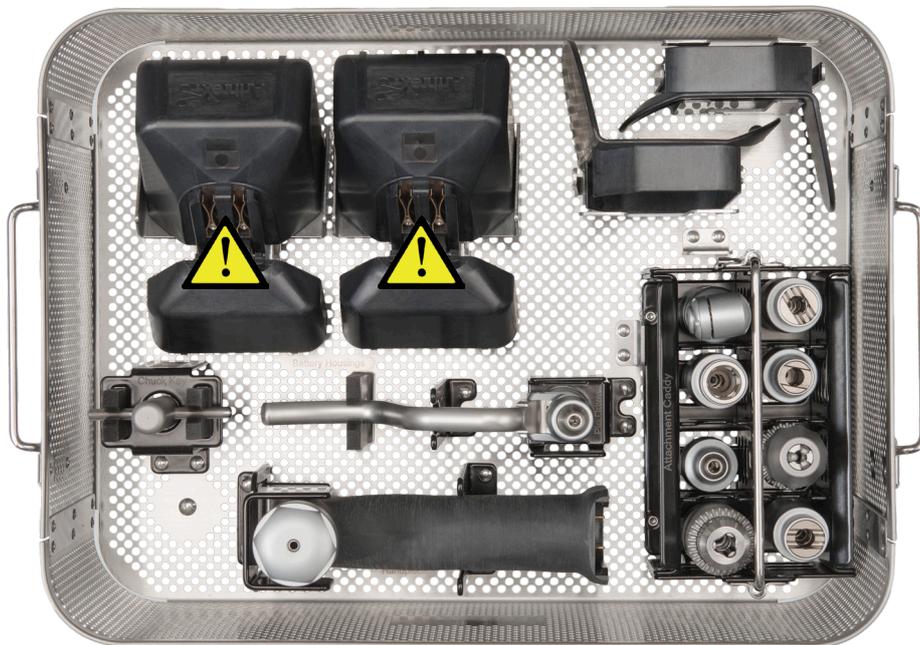
Note: The sterilization time and temperature recommendations listed in this operator's manual are the minimum times required to achieve sterility. If your autoclave temperature is in excess of 134°C (273°F) or if your dry time exceeds 15 minutes, sterility will still be achieved.

The Drillsaw Sports 400 system should be cooled to room temperature and dry prior to use in surgery. Adhere to the recommended dry times to ensure that all electrical contacts are dry in order to prevent malfunctions.

Preparation of Equipped Sterilization Case



Battery housing must be empty and in the open position!



AR-400WMC



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