Instruments

DFU-0198US
Revision 0

IMPORTANT PRODUCT INFORMATION

For U.S. DISTRIBUTION ONLY

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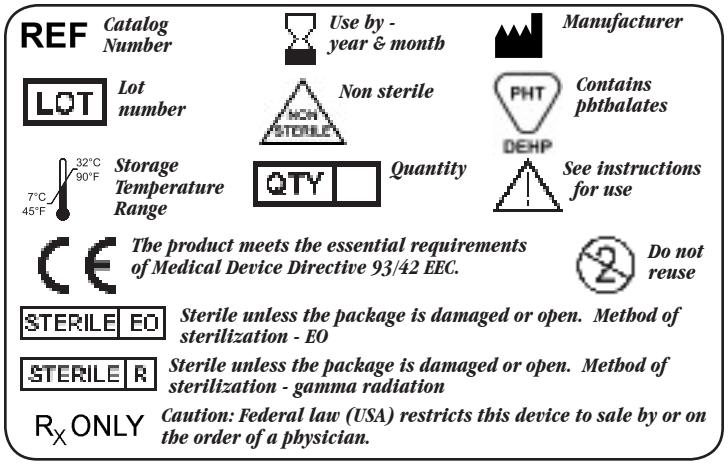

CE: Reusable nonsterile instruments
CE0086: Single-use nonsterile instruments
CE0086: Reusable nonsterile/sterile instruments that may be attached to power

A. REFERENCES

These instructions were developed using the guidance given in the following standards:

- ANSI/AAMI ST79, "Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities"
- ISO 17664: Sterilization of medical devices – Information to be provided by the manufacturer for the processing of re-sterilizable medical devices
- AAMI TIR30: A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices

B. DEVICE DESCRIPTION AND INFORMATION

This device may be a reusable or a single-use nonsterile instrument. Or, it may be a reusable sterile or nonsterile instrument that may be attached to power. Check the package labeling.

Users of this device are encouraged to contact their Arthrex representatives if, in their professional judgment, they require a more comprehensive surgical technique. Arthrex provides detailed surgical techniques in print, video, and electronic formats. The Arthrex website also provides detailed surgical technique information and demonstrations.

C. LIMITATIONS ON REPROCESSING

Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use.

A device labeled as a Single Use device must never be reused. Reuse may pose health and/or safety risks to the patient that can include, but are not limited to cross-infection, breakage resulting in irretrievable fragments, compromised mechanical performance due to wear, lack of or no function, no guarantee of proper cleaning or sterilization of the device.

D. VALIDATION

The recommended cleaning, and sterilization methods in this DFU have been validated in compliance with federal and international guidance/standards. Cleaning, and sterilizing equipment and materials vary in performance characteristics. Therefore, it is the responsibility of the facility/end user to perform the appropriate validation testing.

E. CONTAINMENT AND TRANSPORTATION

It is recommended that instruments are reprocessed as soon as is reasonably practical following use.

Instrument cases and trays are considered reusable devices. Trays should be inspected for visible soil and must be cleaned prior to use. **NOTE:** They can be cleaned manually or in an automatic washer using a detergent.

F. PREPARATION FOR MANUAL AND AUTOMATIC CLEANING

When properly performed, cleaning and/or sterilization do not compromise the use and mechanical performance of these instruments. These instruments are used with or on patients who may harbor both recognized and unrecognized infections. To prevent the spread of infection, all reusable instruments must be thoroughly cleaned and sterilized after use on each patient.

1. No assembly/disassembly of these instruments is required unless stated on the labeling, directions for use, or literature assembly instructions (LAI) pertaining to cleaning and sterilization.
2. Devices that require disassembly should be disassembled prior to cleaning.
3. Remove dried-on soil from devices, especially in areas such as joints and crevices, prior to washing.

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G. INSPECTION AND MAINTENANCE

1. Arthrex non-sterile instruments are precision medical instruments and must be used and handled with care.
2. Inspect the instruments for damage prior to use and at all stages of handling thereafter.
3. Devices with cutting functions or sharp points become dull with continuous use. This condition does not indicate a device defect. This condition indicates normal wear. Dull devices may require replacement if they no longer perform as designed. Inspection prior to use should include verifying the cutting ability and sharpness of these edges.
4. If damage is detected, do not use the device prior to consulting the manufacturer for guidance.
5. Dry instruments thoroughly and lubricate all moving parts with a water-soluble instrument lubricant prior to sterilization.
6. Check instruments for visible soil. Repeat cleaning if soil is visible and re-inspect.

H. MANUAL CLEANING

- Immediate rinsing and cleaning after use with an enzymatic or alkaline cleaning detergent will effectively remove and prevent drying of adherent blood, mucus, etc. Cleaning solutions can include, but are not limited to: ENZOL® enzymatic, Neodisher® Mediclean Forte, and Thermosept® alka clean. **CAUTION: Low acid or high alkaline solutions are not recommended, as they corrode metal parts and anodized aluminum and compromise polymer plastics, such as FEP (Fluorinatedethylenepropylene), ABS (Acrylonitrile Butadiene Styrene), Ultem™, Lexan™, and Cycolac™.**

1. Scrub instrument with a soft brush, paying special attention to areas where debris might accumulate. Always avoid any harsh materials that can scratch or mar the surface of the instrument.
2. Rinse the instrument thoroughly with water following the cleaning process.
3. Check instruments for visible soil. Repeat cleaning if soil is visible and reinspect.
4. **Limited Reuse Shaver Blades and Burrs**. In addition to the previous instructions in Section H:
   - Following each use, disassemble the device by removing the inner tube assembly from the outer tube assembly.
   - Flush the inner lumens of each device with pressurized water flow and then insert a cleaning brush the full length of the stainless steel tubes.

I. ULTRASONIC CLEANING

1. The instrument should be placed in an ultrasonic cleaning unit for a minimum of 20 minutes and processed according to the ultrasonic unit's directions.
2. The instrument should be rinsed thoroughly with water following the ultrasonic process.
3. Check instruments for visible soil. Repeat cleaning if soil is visible and reinspect.

J. AUTOMATIC WASHING

1. Disassemble the device, if applicable.
2. Load the instruments in the washer such that all design features of the device are accessible to cleaning and such that design features that might retain liquid can drain (hinges should be open and cannulations/holes positioned to drain).
3. Run the automatic wash cycle—minimum cycle parameters:
   - 2 minute cold prewash at 68 ± 9°F (20 ± 5°C).
   - 3 minute cleaning wash (enzymatic or alkaline agent) at 140 ± 9°F (60 ± 5°C).
   - 15 second rinse at 140 ± 9°F (60 ± 5°C).
   - 1 minute thermal rinse at 176 ± 9°F (80 ± 5°C).
   - 6 minute drying phase at high temperature.

4. Automatic wash cleaning solutions can include, but are not limited to: ENZOL® enzymatic, Neodisher® Mediclean Forte, and Thermosept® alka clean. **CAUTION: Low acid or high alkaline solutions are not recommended, as they corrode metal parts and anodized aluminum and compromise polymer plastics, such as FEP (Fluorinatedethylenepropylene), ABS (Acrylonitrile Butadiene Styrene), Ultem™, Lexan™, and Cycolac™.**
5. Check instruments for visible soil. Repeat cleaning if soil is visible and reinspect.

K. MANUAL DISINFECTION

1. Instruments should be cleaned before disinfection, as blood albumen will impair the bactericide effectiveness of the solution.
2. Immerse instruments in disinfection solutions for a minimum of 20 minutes.
3. Suitable disinfection solutions can include, but are not limited to: CIDEX®, WAVICIDE®-01, Gigasept®, Kohrsolin®, and equivalent products). Use the supplier's instructions for preparing the solution. **CAUTION: Low acid or high alkaline solutions are not recommended, as they corrode metal parts and anodized aluminum and compromise polymer plastics, such as FEP (Fluorinatedethylenepropylene), ABS (Acrylonitrile Butadiene Styrene), Ultem™, Lexan™, and Cycolac™.**
4. After disinfection, the instruments should be rinsed with distilled water or preferably demineralized sterile water.
5. Dry instruments thoroughly and lubricate all moving parts with a water-soluble, medical-instrument lubricant prior to sterilization.

L. PACKAGING

Singly: Sterilization wrap that has been FDA-cleared for the specified sterilization cycles should be used. Ensure that the wrap is large enough to contain the instrument without stressing the seals.

Sets: Instruments may be loaded into dedicated instrument trays or general-purpose sterilization trays. Ensure that cuttings edges are protected. Wrap the trays in an FDA-cleared sterilization wrap that has been cleared for the specified sterilization cycles, using the appropriate method.

M. STERILIZATION

This device may be provided either sterile or non-sterile. Check the package labeling for more information.

Certain Arthrex devices that may be used during this procedure are provided non-sterile and must be adequately cleaned and sterilized prior to use or re-use.

Sterilizers vary in design and performance characteristics. Cycle parameters and the load configuration should always be verified against the sterilizer manufacturer's instructions.

Cooling – The instrument must be adequately cooled, after being removed from the sterilizer. It should not be touched during the cooling process. Do not place the instrument on a cold surface or immerse in a cold fluid.

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

STERILIZATION PARAMETERS: *FOR THE USA ONLY*:			
INSTRUMENTS & Arthrex Limited Reuse Shaver Blades and Burrs			
	Exposure Temperature	**Exposure Time**	**Drying Time**
Pre-vacuum Cycle	132°C (270°F)	4 Minutes	20 to 30 Minutes
	135°C (275°F)	3 Minutes	16 Minutes

STERILIZATION PARAMETERS: *FOR OUTSIDE THE USA ONLY:*			
INSTRUMENTS & Arthrex Limited Reuse Shaver Blades and Burrs			
	Exposure Temperature	**Exposure Time**	**Drying Time**
Pre-vacuum Cycle	132°C - 135°C (270°F - 275°F)	4 Minutes	20 to 30 Minutes

N. STORAGE

Non-sterile metal devices should be stored in a clean, dry environment. The shelf life of non-sterile devices is not limited; the devices are manufactured from non-degradable material, which does not raise any question of device stability when stored under recommended conditions.

O. SPECIAL PRECAUTION - TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY AGENTS

It is outside the scope of this document to describe in detail the precautions that should be taken for Transmissible Spongiform Encephalopathy Agents (TSE).

The agents for transmission of Creutzfeldt-Jakob disease (CJD) are believed to be resistant to normal processes of sterilization and therefore the normal processing methods of decontamination and sterilization as described above may not be appropriate where CJD transmission is a risk.

In general, the tissues that come into contact with orthopedic surgical instruments are those of low TSE infectivity. However, particular precautions should be taken when handling instruments that have been used on known, suspected, or at-risk patients.

P. CAUTIONS

1. Users of this device are encouraged to contact their Arthrex representatives if, in their professional judgment, they require a more comprehensive surgical technique or more information. Arthrex provides detailed surgical techniques in print, video, and electronic formats. The Arthrex website also provides detailed surgical technique information and demonstrations.
2. To avoid damaging the instruments, do not impact or subject to blunt force any instruments that are designed to be turned or screwed in. When two devices are intended to be threaded together, ensure that they are fully engaged prior to use.
3. Do not use Arthrex instruments for any purpose other than their intended use. Manipulating soft tissue or bone with an instrument not intended for that use may result in damage to the instrument.
4. Instruments with adjustable components must be handled with care. Over-tightening or rough handling of the instrument may damage the locking mechanism. Locking mechanisms with internal polymer components may become weakened after repeated autoclaving.
5. Do not use an instrument that is designed specifically for a particular device with a different device.
6. Flexion of the joint with the instrument in position in the joint may result in bending or breakage of the instrument.

Instrument-Specific Cautions

- **BirdBeak® and Penetrator™**: Do not use the point of the device as a lever or pivot against bone or other hard tissue. If the point is stuck, remove it by putting the instrument straight back. Do not twist, rotate, or move the tip back and forth, because this may cause the point to break off. Keep jaws closed while penetrating; open only when prepared to grasp the desired suture.
- **Depth Guides**: When noted on the depth guide, disassemble the device into components prior to cleaning and sterilization.
- **Limited Reuse Shaver blades**: Use on soft tissue only. These devices are not intended to be used on bone.
- **Limited Reuse Shaver blades and burrs**: Do not use excessive force while operating.
- **Staple Driver**: Do not use the end of the Staple Driver's jaws to seat the staple. This will result in the jaws breaking or bending. Do not use a mallet to strike the end cap of the Staple Driver.
- **Suture Cutters**: Release safety lever before attempting to cut sutures.
- **Left Notch Suture Cutters**: Do not cut into the tied suture knot. This could cause the knot to come loose. Direct visualization of the knot is required.
- **Suture Retrievers**: Use only for suture management. Do not use to grasp suture tightly with the points of the jaws; instead, use a grasping instrument. Do not use to penetrate or manipulate tissue.

Q. WARNINGS

After insertion of the instrument into the joint, do not apply additional flexion to the joint. A piece of a broken instrument can become lodged in soft tissue and/or disappear from the arthroscopic view of the surgical field and can be left in the patient.