



**Reusable Instrument Sets
Instructions for Use**

Description

Arthrosurface Reusable Instrumentation is designed to be used in the sizing, location, and delivery of Arthrosurface components, including articular implants and fixation components. These instruments are designed for repeated use, with proper care and handling.

Instructions for Use

Instructions for use including surgical technique for each of the Arthrosurface Instrument Sets is provided in the appropriate implant Instructions for Use package insert.

Check Instrument Set and implant labeling to ensure product match prior to usage.

Warnings and Precautions

This product is provided NON-STERILE. The product must be properly cleaned and sterilized before each use. Remove and discard any plastic caps or tip protectors before cleaning and sterilizing the instruments. The surgeon shall be thoroughly familiar with the implants, instruments, and surgical technique prior to performing the procedure. Arthrosurface Instrument Sets should be regularly inspected for any signs of wear or damage.

Cleaning

Cleaning instruments by hand rather than by mechanical cleaning will prolong the life of the instruments. Clean all crevices, flutes, and cannulations of all debris, using a soft bristle brush or cleaning stylet. Remove all traces of blood or other residues immediately. Do not allow these to dry. Instruments should be cleaned while submerged in warm water with an appropriate neutral pH detergent. Always follow the manufacturer's instructions when preparing and using detergents. Do not use steel brushes as they can accelerate wear and corrosion of the instruments. Rinse instruments thoroughly with distilled water. Dry instruments immediately after cleaning.

Sterilization

Recommended parameters for steam sterilization are as follows:

| <u>Cycle</u> | <u>Temperature</u> | <u>Minimum Exposure Time</u> |
|--------------|--------------------|------------------------------|
| Vacuum | 270° F/ 132° C | 4 minutes |

Recommended dry time is 30 minutes.

Parameters may vary based on manufacturer, installation or maintenance of sterilization equipment. On-going testing must be performed by the user to confirm inactivation of all forms of microorganisms.

Instrument Trays should be processed in double wrapped configuration using a FDA (or applicable regulatory agency) cleared sterilization wrap. Sterilizing in liquid solutions is not recommended. Do not sterilize at temperatures greater than 275° F/ 135° C.

Note: Arthrosurface does not define the maximum number of uses appropriate for reusable instruments. The useful life of these devices depends on many factors, including the method and duration of each use and handling between uses. Careful inspection and functional test of the instrument before use is the best method of determining the end of useful life.

CAUTION

United States Federal Law restricts this device to sale by or on the order of a physician.

Manufacturer



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This product is covered by one or more of U.S. Patent Nos.
6,520,964; 6,610,067; 6,679,917; other patents and other
patents pending.

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