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X. Summary of Safety and Effectiveness

The ArthroCare Arthroscopic Electrosurgery System™ is a high frequency electrosurgical device intended for use in arthroscopic surgery to resect soft tissue and provide hemostasis. The System is comprised of three components: the Multi-Electrode Probe, the Probe Cable, and the Controller. The System (K943450) was determined substantially equivalent on March 10, 1995.

The bipolar design of the ArthroCare Probe incorporates the return electrode into the shaft of the device. This means that a patient ground pad is not required as with monopolar electrodes. The energy flows back to the Controller via the integral return electrode rather than through the patient's body to the return pad. In addition, the ArthroCare Probe is designed to be operated in a physiological saline environment while the predicate products must be operated in a non-conductive environment, such as sterile water or glycine. This allows ArthroCare to achieve equivalent efficacy in tissue resection with less power requirements.

We believe that the ArthroCare Multi-Electrode Electrosurgical System will be safe and effective when utilized for wrist arthroscopy. There is considerable evidence in the literature as well as animal study data to support this determination. The ArthroCare System was cleared for use in the knee, shoulder, ankle and elbow by the U.S. Food and Drug Administration via Premarket Notification (K943450) in March of 1995. To date, the device has been used in over 10,000 arthroscopic procedures and physicians have reported that the System is effective in arthroscopic tissue ablation and hemostasis. There have been no reports of compromised patient safety in these procedures. We believe that the use of this device in the wrist raises no new issues of safety or efficacy and will simply be an expansion of indications for use to another joint of the body.

The trend in surgery has been to reduce patient trauma, decrease recovery time and decrease health care costs by utilizing minimally invasive surgical techniques. The benefits of arthroscopic surgery are well documented. Compared to open surgical procedures, arthroscopy is a minimally invasive procedure that is significantly more cost effective. Arthroscopic procedures are usually shorter than standard open procedures, require less anesthetic, and the recovery period is shorter.

Advancements in arthroscopic equipment and techniques have expanded the ability of the physician to perform successful arthroscopic procedures in smaller joints, such as the wrist. Wrist arthroscopy is currently performed in smaller numbers than arthroscopy of larger joints, such as the knee and shoulder, however, it has proven to be advantageous for the identical indications. It can provide important diagnostic information and therapeutic intervention, while avoiding the morbidity of open procedures. A review of the literature indicates that the procedure is a safe and effective method that will continue to occupy a niche in the orthopedic surgeon's armamentarium for treating wrist disorders.

An in vivo, arthroscopic animal study was completed and submitted to provide clinical data to support the original 510(k) submission for this device (K943450), cleared March, 1995. The study compared the depth of tissue alteration of meniscal tissue in the intact joints of goats at both the recommended and maximum power settings for the treatment and control devices. The study demonstrated that the depth of tissue alteration and height and width of the ablation lesion were the same for the two devices at the manufacturer's recommended power settings. It was found that there is no significant difference in the safety and efficacy of the ArthroCare Multi-Electrode Arthroscopy System and a standard monopolar electrosurgery device. Please refer to Attachment A (K943450) pages 13, 18 and Appendix B of Attachment B, for a comprehensive discussion of this study.

Scientific journals contain a considerable number of articles discussing wrist arthroscopy. Examples of journal articles describing wrist arthroscopy are included in Appendix D. The literature discusses the currently defined indications for this procedure.

Van Heest (1995) suggests that patients with mechanical wrist pain are the best candidates for arthroscopy as a means to evaluate ligamentous injuries or triangular fibrocartilage complex injuries. His 1995 article entitled, Wrist Arthroscopy, suggests that 8% of arthroscopic procedures are currently performed in the wrist. Van Heest also states that with a systematic approach and careful surgical technique using standard portals, diagnostic or therapeutic wrist arthroscopy can be achieved as a reliable and relatively noninvasive outpatient surgical procedure.

Bain and Roth (1995) confirm that the techniques and portals for wrist arthroscopy are now well established. Resection of soft tissue such as synovium and the triangular fibrocartilage are well documented. Synovectomy has historically been the first line of treatment of joints affected by rheumatoid arthritis. Synovectomy for rheumatoid arthritis appears to slow down, and in some cases, stop the progression of the disease.

Experience in other joints has shown that synovectomy is most successful during the early stages of the disease, prior to severe joint destruction. The concerns with open synovectomy are the prolonged rehabilitation required and the possible loss of motion from arthrofibrosis. Arthroscopic synovectomy of the wrist is indicated in patients for whom conservative medical management has failed.

Cooney (1993) reports a comparison between wrist arthrography and wrist arthroscopy as diagnostic tools for chronic wrist pain. He found arthroscopy to be a more sensitive procedure than arthrography in 20 consecutive patients with confirmed wrist injuries. The was an 86% correlation (the exception - one false negative arthroscopic procedure) between arthroscopy and arthrography in eight patients with triangular fibrocartilage tears. He concluded that wrist arthroscopy is a more valuable technique in determining the location, size, and extent of ligament injuries within the wrist joint.

Cooney (1995) goes on to say that the future of arthroscopy can be expected to impact directly both diagnosis and treatment of pathology of the wrist. He believes that arthroscopy of the wrist remains an important, if not essential, component within the diagnosis of traumatic injuries. In the future, he suggests, a complete diagnostic examination of the wrist will mandate wrist arthroscopy as an essential part of the algorithm of tests for most, if not all patients with wrist instability. Arthroscopy has the specific advantage of being able to document not only the location, size, and extent of ligament damage in the wrist but also to establish the presence of associated dynamic carpal instability.

Bednar and Osterman (1994) state that injuries to the triangular fibrocartilage (TFC) results in incapacitating ulnar-sided wrist pain in many patients who have sustained a prolonged, extension injury to the wrist or a traction injury to the ulnar side of the wrist. Early diagnosis and immobilization in patients without instability of the carpus or distal radioulnar joint results in the rapid resolution of symptoms and return to normal function in the majority of patients. They believe that patients with clinical instability should be acutely treated with arthroscopic evaluation and stabilization, and report 80 to 85% good to excellent results for arthroscopic treatment for TFC tears.

Savoie (1995) describes the indications for wrist arthroscopy as those patients for whom non-operative treatment fails. He states that intra-articular pathology of the wrist responds well to arthroscopic intervention. The group of patients who present with continued pain despite normal tests and failed physical therapy represent a diagnostic dilemma for the physician. Arthroscopy can help to solve the dilemma for patients with the presence of

clinically reproducible symptoms and failure of an adequate trial of non-operative treatment.

Whipple (1994) describes the radioulnar joint as a relatively simple articulation between two bones, however, goes on to say that the ligamentous support system for this joint is relatively complex. The ligaments supporting the distal radioulnar joint (DRUJ) include the joint capsule, the volar and dorsal ulnocarpal ligaments, and the triangular fibrocartilage (TFC). He believes that arthroscopy has provided a minimally invasive means of evaluating the distal radioulnar joint, and finds it especially useful for soft tissue disorders involving synovium, articular cartilage and the TFC.

Buterbaugh (1994) states that wrist arthroscopy is now an accepted technique in the evaluation of radiocarpal intra-articular pathology. This article describes the technique for wrist arthroscopy in great detail. He closes by confirming that wrist arthroscopy is a valuable tool in defining the normal anatomic structures of the radiocarpal joint. He suggests care to view both the superficial and deep structures of the wrist joint and to consider the consequences of changes within the ligamentous supports. With understanding of the normal anatomic structures, pathologic problems can be readily identified and treated successfully.

Review of the literature reveals that relatively few complications are associated with wrist arthroscopy. The incidence of complications for joints other than the wrist are estimated by Warhold and Ruth (1995) to be approximately 0.59%. Arthroscopy of each joint is associated with the unique hazards related to the anatomic obstacles or to the specific procedure performed. The complications associated with wrist arthroscopy as reported by Warhold and Ruth (1995) include stitch abscess, inclusion cysts, and mild sympathetic dystrophy. Other potential complications include:

1. those related to traction and arm positioning,
2. those related to the establishment of portals and the introduction of instruments,
3. procedure-specific complications, and
4. miscellaneous complications associated with arthroscopy in general.

With specific precautions, the complications associated with wrist arthroscopy can be largely avoided. A thorough knowledge of and careful observance of anatomic land marks will prevent damage to the nerves and arteries of the wrist during arthroscopy. Traction to distract the wrist sufficiently will guard against scuffing of the cartilage surfaces and limiting the force and time of traction can serve to prevent nerve traction disorders.

In the Warhold and Ruth article mentioned above, the authors state that arthroscopy of the wrist is an equipment dependent procedure. Few instruments can substitute for the small tools specifically designed for used in the wrist joint. The smallest ArthroWand, sized at 2.5mm, is perfect for use in the wrist.

Physicians are currently performing arthroscopic procedures in the wrist joint and will continue to do so. The procedure has demonstrated utility for defined indications and can offer an attractive option to a patient faced with the prospect of a conventional open surgical procedure and in conjunction, the procedure offers the physician an additional valuable tool in wrist surgery. As in other joints of the body, the ArthroCare Multi-Electrode Electrosurgery System will be safe and effective when used in arthroscopic procedures of the wrist joint.