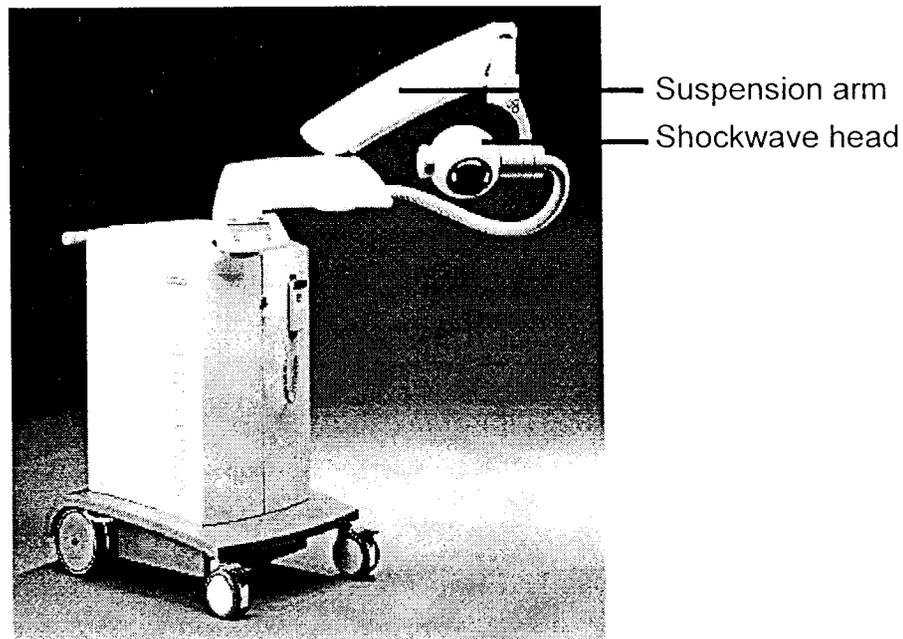


1 Patient Information
2 Extracorporeal Shock Wave Therapy (ESWT)
3 for Lateral Epicondylitis with Siemens' SONOCUR[®] Basic
4

5 **What is extracorporeal shock wave therapy (ESWT) ?**

6 "Extracorporeal" means "outside the body". Shock waves are created by strong
7 acoustic (sound) energy pulses. Extracorporeal shock wave therapy has recently
8 been found to be effective to treat lateral epicondylitis, sometimes called tennis
9 elbow, a condition that causes pain in the elbow of the affected arm. Your ESW
10 therapy will be performed with a device called SONOCUR Basic.

11
12 SONOCUR Basic is a shock wave generator, very similar to the shock wave devices
13 used to treat kidney stones without surgery. The spherical shock wave head holds a
14 kind of loud speaker that drives acoustic pulses through a lens and a water channel
15 to the affected elbow. The shock head is attached to a suspension arm which allows
16 the shock head to reach to a patient's arm if the patient is in a sitting or lying position.
17 (see figure 1).



33
34 **Figure 1: SONOCUR Basic**

35
36 Trained medical professionals will operate the SONOCUR Basic system. These
37 professionals are familiar with how to treat tennis elbow with ESWT. They will focus
38 shock waves by moving the shock wave head and by adjusting shock waves to go
39 deep enough to give you the best treatment.

40 **Who should consider having ESWT for tennis elbow?**

41 ESWT with SONOCUR Basic is for patients who have had elbow pain for at least 6
42 months and who have tried other methods for treating their elbow pain. In the
43 SONOCUR Basic clinical study, the treated patients had failed to respond to at least
44 two of the following three conventional therapy programs:

- 45 • At least 4 weeks of physical/occupational therapy
- 46 • At least 4 weeks course of NSAIDs (non-steroidal anti-inflammatory drugs such
47 as aspirin, Tylenol (acetaminophen), Advil (Ibuprofen) or Aleve (Naproxen))
- 48 • Local steroid injection(s)

49
50 **Who should not have ESWT for tennis elbow?**

- 51 • There are no known contraindications to ESWT with the SONOCUR Basic for
52 treatment of lateral epicondylitis.

53
54
55 **What else should I know about the SONOCUR Basic treatment?**

- 56 • Patients with tennis elbow affecting both arms at the same time or who have had
57 previous surgery for this condition have not been studied. Therefore, no
58 statement regarding the effectiveness of ESWT for these conditions can be made.
- 59 • You must stop taking NSAIDs (non steroidal anti-inflammatory drugs such as
60 aspirin) a week before you have ESWT to allow time for this medicine to
61 completely pass through and out of your body. You should do this because these
62 medications may cause problems with blood clotting. If this happens, bruising is
63 more likely to occur.

64
65 The safety and effectiveness of the SONOCUR Basic ESWT has not been
66 established for:

- 67 • Pregnant women
- 68 • Patients younger than 18 years of age.
- 69 • Patients with a coagulation abnormality, thrombopathy, infection, tumor, cervical
70 compression syndrome (a nerve in the upper neck is compressed causing pain
71 similar to tennis elbow), cervical or upper extremity arthritis, local arthrosis,
72 neurologic abnormality, or radial nerve entrapment (the nerve, passing the elbow,
73 is compressed causing pain similar to tennis elbow)
- 74 • Patients who have had previous surgery for lateral epicondylitis
- 75 • Patients who suffer from severe systemic diseases that may lead to sensory
76 changes or nerve related pain. For example, this may include diseases such as
77 gout, diabetes mellitus, rheumatoid arthritis.
- 78 • Patients with cardiac pacemaker

- 79 • Patients who received physical or occupational therapy less than four (4) weeks
80 prior to ESWT
- 81 • Patients who received a local steroid injection less than six (6) weeks prior to
82 ESWT.
- 83 • Patients with tennis elbow affecting both arms or who have had previous surgery
84 for this condition

85

86 Your doctor can provide you with additional information about these and other
87 conditions, and how they might affect the decision to have ESWT.

88

89 **What other treatments are available for treating tennis elbow?**

90 Doctors know that some people who have elbow pain get better with time, even with
91 no treatment. Other people get better after trying one or several non-surgical
92 treatments, which include:

- 93 • Rest from excessive or abusive activity
- 94 • Application of heat or cold
- 95 • Physical conditioning exercises
- 96 • Physical/occupational therapy, including ultrasound therapy
- 97 • Over-the-counter pain relievers, such as aspirin or Tylenol (acetaminophen)
- 98 • Prescription pain relievers
- 99 • Non-steroidal anti-inflammatory medications (NSAIDs), such as aspirin, Tylenol
100 (acetaminophen), Advil (Ibuprofen) or Aleve (Naproxen)
- 101 • Steroid injections (Cortisone)

102

103 If these conservative therapies are not successful, another alternative is to have
104 surgery.

105

106 **What adverse effects could happen with SONOCUR Basic treatment?**

107 The following effects were observed during the clinical trials of SONOCUR Basic:

- 108 • Pain during and immediately after treatment was most commonly reported.
- 109 • Nausea was the second most commonly reported side effect.
- 110 • ESWT may cause sweating, dizziness, tremor, paleness and may temporarily
111 widen blood-vessels. Most reported events were mild in severity and resolved
112 within 24 hours without any further treatment.
- 113 • ESWT may cause skin reddening or bruising of the treated elbow, which usually
114 clears within a few days after the treatment.
- 115 • ESWT may cause muscle pain (myalgia) and muscle tension (hypertonia). The
116 reported side effects included muscle, forearm, and wrist soreness, cramps, and

- 117 spasms. Most of these reported side effects were mild in severity and resolved
118 within 48 hours of treatment, without any further treatment.
- 119 • ESWT may cause joint stiffness. This side effect disappeared within 48 hours of
120 treatment without any further treatment.
 - 121 • Some patients reported numbness and tingling sensations, most of which radiated
122 down from the elbow to the wrist. Most of these sensations resolved without
123 treatment.

124

125 Potential adverse events not seen during the study include:

- 126 • Neuropathy (problem with the nervous system)
- 127 • Tendon rupture
- 128 • Local hematoma (bruising)
- 129 • Misdirection of energy

130

131 **What happens during the SONOCUR Basic treatment?**

132 If your doctor recommends SONOCUR Basic treatment he/she will feel the painful
133 area in order to locate the exact point of tenderness. This point may be marked on
134 your skin with a color marker. You will be treated sitting in a chair or lying down with
135 your arm supported by an arm rest (See figure 2). Prior to the treatment, a coupling
136 gel will be applied to the treatment area by the operator. This gel makes it possible for
137 the shock waves to enter your arm. Next, the SONOCUR Basic's shockwave head is
138 applied to the treatment area (the marked spot). The treatment will be started with very
139 low intensity pulses. You may experience some irritation in your arm every time you
140 hear the "clapping sound" produced by the system's "loud speaker". The irritation that
141 you feel should be in the area of your elbow pain. If this is not the case, you should
142 move your arm with the operator's help until you feel the treatment in the area of your
143 pain.

144

145

146

147

148 **Figure 2:**

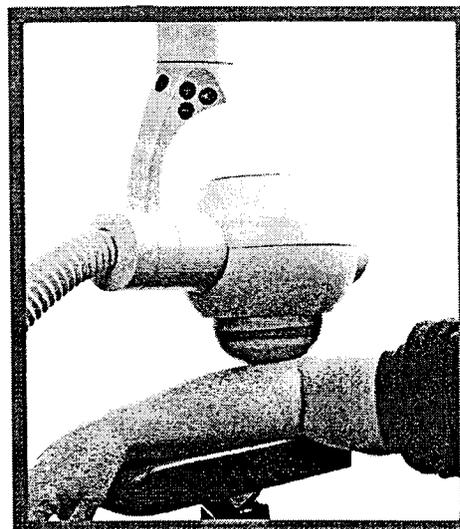
149 Shockwave head and patient's
150 arm in treatment position

151

152

153

154



155

156

157 After about 100 pulses you may experience some kind of local numbness and the
.58 operator will increase the energy to the treatment level. This may cause more pain
159 that should eventually wear off after a couple of hundred pulses. If the pain is too
160 uncomfortable, you should tell the operator so that the shockwave head may be
161 moved. A total of 2100 pulses will be applied during a single treatment session. One
162 treatment session will take about 20 minutes and is performed as an outpatient
163 procedure. A complete therapy for tennis elbow usually requires 3 treatment sessions
164 with a week pause between sessions.

165

166 **What are the expected results from ESW treatment?**

167 In a clinical study it was shown that SONOCUR Basic ESWT significantly reduced
168 pain and improved functional activity compared to a placebo (mock) group 12 weeks
169 after the last treatment. 114 patients participated in the clinical study. The patients
170 were randomly distributed in two groups. One group (58 patients) served as a
171 placebo group where patients received a “mock” treatment. The patients in the other
172 group (56 patients) received the SONOCUR Basic treatment.

173

174 During the study, patients were asked to comment on their level of pain and their
175 ability to use their arm (functional activity). With regards to elbow pain, patients were
176 asked to score their level of pain on a scale of 0 to 100. A score of 0 meant that they
177 felt no pain and a score of 100 meant that they felt a great deal of pain. The average
178 pain score for patients who received the active treatment was 74 when they entered
179 the study and 37.6 at 12 weeks. The average score for the placebo patients was
180 75.6 when they entered the study and 51.3 at 12 weeks. This was an average
181 improvement of 49% for the active treatment group and 32% for the placebo group
182 (see Table 1, below).

183

184 Each patient who experienced at least a 50% reduction in pain was considered a
185 study success. At 12 Weeks, 61% (34/56) of the patients in the SONOCUR Basic
186 treatment group reported at least 50% reduction in pain level, compared to the time
187 they entered the study. In the placebo (mock) group, only 29% (17/58) of patients
188 reported the same level of improvement at 12 weeks. In addition, less patients in the
189 active treatment group (17/56, or 30.4% patients) compared to the placebo group
190 (30/58, or 51.7% patients) used pain medications during the study.

191

192 In addition to pain reduction, functional improvement was also examined using an
193 Upper Extremity Functional Scale, or UEFS, test. For this test, patients in the study

194 were asked to score their ability to perform specific daily chores (such as opening
 195 jars/doors, washing dishes) on a scale from 1 to 10, with a score of 1 meaning that
 196 the patient had no problem at all and a score of 10 meaning that the patient could not
 .97 perform the chore. Between the time they entered the study and 12 weeks, the
 198 average score reported for all placebo patients changed from 4.6 to 3.2 (an average
 199 improvement of 31%), and the mean score for all active treatment group patients
 200 changed from 4.7 to 2.3 (an average improvement of 51%).

201
 202 In addition to the pain and functional activity (UEFS), patients were also asked to
 203 score their overall impression of their tennis elbow condition (on a scale of 0-100,
 204 with a score of 100 being the worst possible condition) and their ability to perform
 205 specific daily activities which they had problems doing before treatment (such as
 206 playing tennis) on a scale of 1 to 10, with a score of 1 being the best case and 10
 207 being the worst case. The results of these tests are also shown in table 1 below.

208
 209 **Table 1. Percent Improvement at 12 Weeks**

	SONOCUR Basic			Placebo (Mock)		
	average score at beginning of study	average score at 12 weeks	% improvement	average score at beginning of study	average score at 12 weeks	% improvement
Pain	74	37.6	49%	75.6	51.3	32%
UEFS	4.7	2.3	51%	4.6	3.2	31%
Activity Evaluation	7.7	3.5	55%	7.4	5	33%
Overall Impression	70.3	32.8	53%	66	46.2	30%

210
 211
 212 **If you have additional questions about ESWT with SONOCUR Basic, please be**
 213 **sure to talk to your doctor.**

214
 215 **Printing date:** ~~March 27~~ June 21, 2002

216
 217 **Contact Information:**

218 Siemens Medical Solutions, Inc. USA
 219 186 Wood Avenue South
 220 Iselin, New Jersey 08830
 221 Telephone: 732-321-4500
 222 Web Address: www.siemensmedical.com