

1 **Clinical Practice Guideline: Intradermal Needles and Ear Tacks**

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3 **Date of Implementation: February 9, 2006**

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5 **Product: Specialty**

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8 **GUIDELINES**

9 American Specialty Health – Specialty (ASH) considers the use of intradermal needles  
10 (i.e., acupuncture devices that puncture and remain in the patient’s skin upon the patient  
11 leaving the office) such as needle implants or ear tacks not medically necessary due to risk  
12 of direct harm.

13

14 Due to the potential for direct harm from this procedure, including infection and injury,  
15 practitioners are strongly recommended to use the safer alternative of ear seeds, press balls,  
16 as well as other acupressure devices that do not puncture the skin. For more information,  
17 see the *ASH Techniques and Procedures Not Widely Supported as Evidence Based (CPG*  
18 *133 – S)* clinical practice guideline.

19

20 Patients must be informed verbally and in writing of the nature of any procedure or  
21 treatment technique that is considered experimental/investigational or unproven, poses a  
22 significant health and safety risk, and/or is scientifically implausible. If the patient decides  
23 to receive such services, they must sign a *Member Billing Acknowledgment Form* (for  
24 Medicare use *Advance Beneficiary Notice of Non-Coverage form*) indicating they  
25 understand they are assuming financial responsibility for any service-related fees. Further,  
26 the patient must sign an attestation indicating that they understand what is known and  
27 unknown about, and the possible risks associated with such techniques prior to receiving  
28 these services. All procedures, including those considered here, must be documented in the  
29 medical record. Finally, prior to using experimental/investigational or unproven  
30 procedures, those that pose a significant health and safety risk, and/or those considered  
31 scientifically implausible, it is incumbent on the practitioner to confirm that their  
32 professional liability insurance covers the use of these techniques or procedures in the event  
33 of an adverse outcome.

34

35 **DESCRIPTION/BACKGROUND**

36 Intradermal needles are typically short, sterile needles made of stainless steel that are  
37 inserted just under the skin. There are two common types of intradermal needles. One has  
38 about a 3mm needle and a flat wire head resembling a tiny thumbtack. These small tack-  
39 shaped needles are generally applied to acupuncture points on the ear but can be placed on  
40 other body areas as well. The other type of needle is about a centimeter long and has a  
41 small head resembling a grain of wheat. These needles are inserted horizontally under the  
42 skin on various body areas. Once embedded, the handle or exposed part of the needle is

1 covered with an adhesive (e.g., medical tape) to protect against infection and hold the  
2 needle in place. Typically, intradermal needles are only left in place for a few days.

3  
4 Intradermal needles are intended to provide continuous stimulation of acupuncture points  
5 by remaining embedded in the skin. They are typically used to treat certain chronic and/or  
6 painful diseases in which patients may benefit from prolonged needle retention. Examples  
7 of conditions in which intradermal needles may have traditionally been used include  
8 headache, stomachache, asthma, insomnia, and dysmenorrhea. Embedded intradermal  
9 needles have also been used to treat patients seeking assistance in tobacco cessation or  
10 weight loss.

## 11 **EVIDENCE REVIEW**

12 In one controlled, double-blind study, Kotani et al. (2001) concluded that postoperative  
13 pain, analgesic requirements, and opioid-related side effects after both upper and lower  
14 abdominal surgery were reduced with preoperative insertion of intradermal needles at  
15 acupuncture points 2.5cm from the spinal vertebrae (along the urinary bladder meridian in  
16 acupuncture).

17  
18  
19 Another study by Kotani, Kushikata, Suzuki et al. (2001) tested the hypothesis that  
20 insertion of intradermal needles into painful abdominal scars reduces scar pain. Data  
21 suggest the insertion of intradermal needles into painful points is an effective treatment for  
22 intractable abdominal scar pain.

23  
24 Acupuncture's usefulness in obesity management has not yet been fully evaluated. In their  
25 review Lacey et al. (2003) surveyed and critically evaluated the available descriptive and  
26 controlled trials of acupuncture for enhancing weight loss. The underlying principles of  
27 acupuncture point stimulation are described, with an emphasis on auricular (ear)  
28 acupuncture, the method most often chosen for obesity studies. The difficulties of selecting  
29 suitable placebo controls are highlighted. To date, most trials have been descriptive in  
30 nature, of short duration (less than or equal to 12 weeks), and designed using nonstandard  
31 treatment protocols. Sacks (1975) performed a retrospective review of patients treated for  
32 drug addiction, obesity, alcoholism, and excessive smoking. The studies used ear tacks and  
33 body points for various lengths of time in 1,030 cases of obesity. Success rates were noted  
34 as 25% excellent success (weight loss of 8–10 lb/month), 50% good success (control of  
35 eating habits and half of their individual goal being met), while 20% were “not influenced  
36 at all.”

37  
38 Further careful study of acupuncture's potential usefulness as an adjunct in weight  
39 management is recommended.

40  
41 Since acupuncture provides analgesia it might be expected to reduce the need for  
42 conventional anesthetic drugs during general anesthesia. Akca and Sessler (2002) discuss

1 four (4) double-blind, placebo-controlled studies evaluating acupuncture's ability to reduce  
2 analgesic or anesthetic requirement. Three studies (Greif et al., 2002; Morioka et al., 2002;  
3 Taguchi et al., 2002) examined whether transcutaneous electrical stimulation of some  
4 acupuncture points reduces anesthetic requirement. None of these three studies showed  
5 that the stimulation of the acupuncture points produces clinically important reductions in  
6 anesthetic requirement. In contrast, Kotani et al. (2001) tested the hypothesis that  
7 preoperative insertion of intradermal needles in the bladder meridian reduces postoperative  
8 pain and opioid requirement and showed that at least some acupuncture techniques provide  
9 substantial postoperative analgesia and significantly reduce opioid requirements.  
10 Usichenko (2005) showed that auricular acupuncture with press needles retained in the  
11 ear for three days helped reduce the analgesic needs of patients after total hip arthroplasty.  
12 Deng et al. (2008) sought to determine whether intradermal acupuncture reduced pain or  
13 analgesic use in patients with cancer after thoracotomy compared with a sham acupuncture  
14 technique (control). Results demonstrated no statistically significant differences between  
15 groups for chronic pain assessments at 60 and 90 days, in-patient pain, and medication use  
16 in the hospital and after discharge.

17  
18 One RCT ( $n = 90$ ) evaluating the effectiveness of auricular acupuncture for reducing cancer  
19 pain found a positive effect for acupuncture using steel ear implants at acupuncture points  
20 where an electrodermal signal was detected (Alimi et al., 2003). In addition a pilot RCT  
21 ( $n = 43$ ) evaluating the effectiveness of gold beads implanted at 5 acupuncture points in  
22 patients with osteoarthritis (OA) of the knee found preliminary evidence of effectiveness  
23 for self-assessed pain, stiffness, and function; and for surgeon-assessed knee score and  
24 knee function (Nejrup et al., 2008).

25  
26 Lan et al. (2015) completed a systematic review and meta-analysis on auricular  
27 acupuncture with seed or pellet attachments for primary insomnia. A total of 15 studies  
28 were identified as eligible for review. Statistical analyses revealed a positive effect of  
29 auricular acupuncture for primary insomnia, however considering the poor methodology  
30 and other design weakness, the evidence is not adequate to strongly support this treatment  
31 of insomnia. Jing, et al (2021) reported on a forty-five-study, 3058-patient meta-analysis  
32 of intradermal acupuncture for insomnia. Intradermal acupuncture was compared to  
33 acupuncture, no acupuncture, and control groups with and without acupuncture. Scores on  
34 the Pittsburgh Sleep Quality Index improved when intradermal acupuncture was used.  
35 However, the level of evidence was rated very low to low due to risk of bias and lack of  
36 conformity between studies.

37  
38 Garner et al. (2018) examined the use of auricular acupuncture applying a standard protocol  
39 for chronic pain and insomnia. The aims of this research were to assess the feasibility and  
40 credibility of auricular acupuncture, to evaluate its effects on pain severity and interference  
41 scores, and to assess its effects on insomnia severity over an 8-day period. Forty-five  
42 participants were randomized to either an auricular acupuncture group (AAG) or a usual

1 care group (CG) on study day 4. A standard auricular acupuncture protocol was  
2 administered, with penetrating semi-permanent acupuncture needles in place for up to  
3 4 days. The main outcome measures were feasibility of conducting the study, credibility of  
4 auricular acupuncture as a treatment modality, Brief Pain Inventory pain severity and  
5 interference scores, and Insomnia Severity Index (ISI) scores. There was high interest in  
6 the study and the retention was 96%. Credibility of auricular acupuncture as a treatment  
7 was high in both groups, which may have biased the results. The use of auricular  
8 acupuncture led to significant within- and between-group reduced pain severity and  
9 interference scores, compared to the CG. Both groups showed within-group decreased ISI  
10 scores. However, the AAG showed significant between-group reduced ISI severity scores  
11 compared to the CG. Authors concluded that this treatment may be an option for treating  
12 military beneficiaries who have chronic pain and insomnia. Study limitations require  
13 further research to substantiate results.

14  
15 Luo et al. (2020) evaluated the effect of hand-ear acupuncture on chronic low-back pain  
16 (cLBP). All 152 participants with cLBP were randomly assigned to hand-ear acupuncture  
17 ( $n = 54$ ), standard acupuncture ( $n = 50$ ), or usual care groups ( $n = 48$ ). Eighteen treatments  
18 were provided over 7 weeks. Back-related dysfunction and symptom severity were  
19 assessed by the Roland-Morris Disability Questionnaire (RMDQ) and the Visual Analogue  
20 Scale (VAS), which were collected at baseline, 2 months and 6 months post treatment.  
21 Authors concluded that both of the hand-ear acupuncture and standard acupuncture modes  
22 have beneficial and persistent effectiveness against cLBP compared with the usual care.  
23 Furthermore, hand-ear acupuncture was significantly more effective than the standardized  
24 acupuncture, especially in the long term. Moura et al. (2019) compared the efficacy of  
25 Chinese and French ear acupuncture in people with chronic back pain in an open,  
26 randomised and controlled clinical trial. For the ear acupuncture treatment, semi-  
27 permanent needles were inserted and fixed with beige anti-allergic micropore. One hundred  
28 and eleven people were selected and randomised into three groups: Chinese ear  
29 acupuncture; French ear acupuncture; and Control. Results demonstrated that pain severity  
30 was significantly decreased by Chinese ear acupuncture throughout the intervention period.  
31 Both types of ear acupuncture affected pain interference with daily activities. However, in  
32 the comparison between initial and final evaluations, only Chinese ear acupuncture  
33 produced statistically significant results. A reduction in physical disability was observed  
34 in both ear acupuncture-treated groups during the intervention period. At follow up, the  
35 mean difference between Chinese and French ear acupuncture revealed that the Chinese  
36 procedure had a greater beneficial effect on this parameter. Authors concluded that the  
37 individualised treatment based on the Chinese precepts showed, in an overall evaluation,  
38 better results for management of chronic back pain in the present study.

39  
40 In a randomized, controlled trial, Usichenko et al. (2022), participants undergoing elective  
41 c-section deliveries were equally randomized to an acupuncture group or placebo group of  
42 60 patients each. All participants received spinal anesthesia. Another 60 patients received

1 standard care with post-operative analgesia. The treatment group received auricular and  
2 body acupuncture with indwelling intradermal needles remaining in place for three days  
3 after the procedure. Patients in the placebo group received non-penetrating placebo  
4 needles. Patients in the active treatment group demonstrated lower mean pain intensities,  
5 more rapid mobilization, and earlier urinary catheter removal than the standard and placebo  
6 groups. Adverse events reported for the acupuncture group were fatigue, nausea and  
7 vomiting, bradycardia all at comparable rates to the placebo acupuncture and standard care  
8 groups. Two patients from the acupuncture group reported unpleasant sensations at the  
9 acupuncture needle sites.

10  
11 A review was performed of battlefield acupuncture including five trials and 344  
12 participants who received semi-permanent intradermal ear needle treatments (Yang et al.,  
13 2022). The treatments showed no significant efficacy for reducing pain levels when  
14 compared to no intervention, usual care, and sham. Adverse events were few and all were  
15 mild and transitory. The studies were said to be of poor methodological quality and the  
16 authors recommended randomized controlled trials in the future.

17  
18 Adverse effects from the use of intradermal needles have also been observed. Yamashita  
19 et al. (2001) reviewed Japanese literature and noted 124 cases of adverse events with  
20 acupuncture; Forty-eight cases were caused by needle breakage including 26 cases of  
21 intentionally embedded needles.

22  
23 Ou et al. (2023), conducted a systematic review and network meta-analysis including 3046  
24 participants and 32 RCTs investigating acupuncture for cancer-related insomnia.  
25 Acupuncture and moxibustion were more effective than sham, Western treatments, and  
26 routine care. The most effective therapies were acupuncture and moxibustion together,  
27 acupuncture with electric stimulation, auricular acupuncture, intradermal needling along  
28 with routine care, and intradermal needling alone. No serious acupuncture or moxa-related  
29 events were reported in the studies. A few cases of non-serious acupuncture side effects  
30 (hematomas and local pain) were recorded. The incidence of adverse events was much  
31 higher in the groups receiving medication than the acupuncture-moxa groups.

32  
33 A systematic review and meta-analysis of acupuncture-related migraine therapies by Song  
34 et al. (2022) included thirty-nine studies of 4379 patients and thirteen different acupuncture  
35 therapies. For reduction of pain scores, acupoint injection and needle implantation were  
36 the most effective methods. Embedded needling was the second most effective therapy for  
37 reducing migraine days with electroacupuncture coming in first. Embedded needling was  
38 best for reducing the duration of the migraine. One study of embedded needling reported  
39 the retention time of 24 hours. The one study with implanted needle did not record the  
40 retention time. There were no reported adverse events in the embedded or implanted  
41 needling groups.

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