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Identification of Orthopedic Device Manufacturer

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ABSTRACT: Orthopedic devices recovered in association with skeletal remains offer information that can assist in identification. Frequently, surgical devices contain information that allow the identification of the manufacturer. Since March 1, 1993 a tracking system is in place that may allow the identification of the individual patient. A recent survey of the manufacturing companies results in summary information on the identification labels on products that allow them to be traced.

KEYWORDS: physical anthropology, human identification, orthopedic devices, surgical implants, identification, manufacturers

Increasingly, orthopedic devices are recovered in association with human remains. Since such devices represent surgical implants, they potentially offer information that can be used to identify the individual. With some fragmented skeletal remains and commercial cremations, such devices may present the most significant information leading to identification. Because thousands of orthopedic implant devices, cardiac pacemakers and valves, etc., are manufactured and distributed worldwide, they can be very useful in postmortem identification [*1,2*]. Sathyavagiswaran et al. [*3*] reported how a pacemaker was traced to the manufacturer to identify an individual who otherwise would have been difficult to identify.

Praemer et al. reported that in 1988 11,051,000 (or 4.6% of the United States' population) had at least one medical device implant [*4*]. These include such devices as artificial heart valves, artificial joints, fixation devices, pacemakers, ear vent tubes, infusion pumps, dental implants, silicone implants, artificial veins and arteries, and intraocular lens implants [*4*]. Considering that many individuals have multiple implants and most implants have multiple parts, the number of potentially identifiable pieces is quite large. For example, Praemer et al. reported 816,000 hip replacement procedures in 1988 [*4*]. Typically, this procedure includes a femoral stem and head, and acetabular shell, liner, and three to five screws. The 816,000 procedures conducted in 1988 may have resulted in over 5 million potentially identifiable pieces being implanted.

A total knee procedure can entail implantation of a femoral component, a tibial tray, a tibial liner, four screws, a patella component, and a patella liner for a total of nine separate pieces. The 521,000 knee procedures reported to have taken place in 1988 [*4*] would result in nearly 4.7 million implanted pieces.

The presence of such devices do not automatically signal that human remains are represented. One such case submitted to the FBI laboratories from the state of Alaska consisted of a bone fragment about 70 mm in length with a surgically implanted metal plate bridging an ununited fracture (pseudoarthrosis) in the midshaft [*5*]. Although the presence of the plate initially suggested a human origin, radiographic and microscopic studies later confirmed the nonhuman, likely canid origin of the bone. Although some devices are manufactured specifically for use by veterinarians, most are used in treating both humans and nonhumans. Thus usually, the device itself will not indicate if the remains are human or nonhuman, but it may present other information useful in identification, particularly if the manufacturer can be identified.

Tracking of Medical Devices

Acting under the Safe Medical Devices Act (SMDA), the Food and Drug Administration of the Department of Health and Human Services requires device manufacturers and importers to be able to track implanted devices to the patient [*6*]. Effective March 1, 1993, manufacturers have been required to implement a system that will provide information to the FDA within a fixed time period regarding the date certain devices were shipped, the patient receiving the device, the physicians involved in the initial surgery and subsequent care, and other relevant information. Under these rules and regulations, distributors of the devices also are required to maintain records that facilitate tracking.

As a consequence of these regulations, certain surgical devices manufactured after March 1, 1993 should be easily traced not only to the manufacturer, but also to the distributor, physicians involved, and the patient. The devices themselves and associated medical records should provide unique information to facilitate positive identification.

For many years (even prior to the FDA regulations) the orthopedic manufacturers have routinely marked individual implants with a unique serial and/or production lot number. In many cases, a corporate identifier (either a logo or name) is placed on the device. In some cases, the device may be so small (for example, a screw for facial reconstruction) that only the logo will be present. Some devices may be so small that even that level of identification is precluded.

Survey of Manufacturers

To facilitate the tracking process within a forensic context, we surveyed manufacturers of orthopedic products. Nine manufacturers responded, providing information about their product labeling. The responding companies and their identifier information are

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TABLE 1—*Orthopedic manufacturers product identification.*

Name and Address	Phone/Fax Numbers	Contact	Identifier
Ace Medical Company 14105 South Avalon Boulevard Los Angeles, CA 90061	Phone: 1-800-421-2871 Fax: 310-329-6085	C. Pering	The word "ACE" over a stylized crutch and caduceus (Fig. 1d)
Biomet P.O. Box 587 Warsaw, IN 46581-0587	Phone: 219-267-6639 Fax: 219-267-8137	J. J. Wagoner	One of the following: 1. B 2. BIOMET 3. BMT 4. OEC 5. Triangle with OEC inside
Biopro 17 17th Street Port Huron, MI 48060	Phone: 1-800-252-7707	Dr. L. Serafin	The word "BIOPRO"
Joint Medical Products 860 Canal Street Stamford, CT 06902	Phone: 203-348-4841	J. Smith	The word "SROM" on knee components only
Ortomet, Inc. 6301 Cecilia Circle Minneapolis, MN 55439-2713	Phone: 612-944-6112 Fax: 612-944-1389	D. Crane	The word "ORTHOMET"
Synthes (USA) 1690 Russell Road P.O. Box 1766 Paoli, PA 19301	Phone: 215-647-9700	J. Disegi	Stylized pelvis (Fig. 1f)
Howmedica, Inc. 359 Veterans Boulevard Rutherford, NJ 07070-2584	Phone: 201-507-7300 Fax: 201-507-7254	C. Lawler	The letter "V" in a shield or the letter "H" in an enclosed area (These marks also serve to identify manufacturing site and material of construction.) (Figs. 1a and 1b)
Zimmer P.O. Box 708 Warsaw, IN 46580-0708	Phone: 219-267-6131 Fax: 219-372-4550	R. Crowninshield	The letter "Z" inside a circle (Fig. 1c)
Osteonics 59 Route 17 Allendale, NJ 07401-1677	Phone: 201-825-4900	R. Koch	Stylized femur (Fig. 1e)

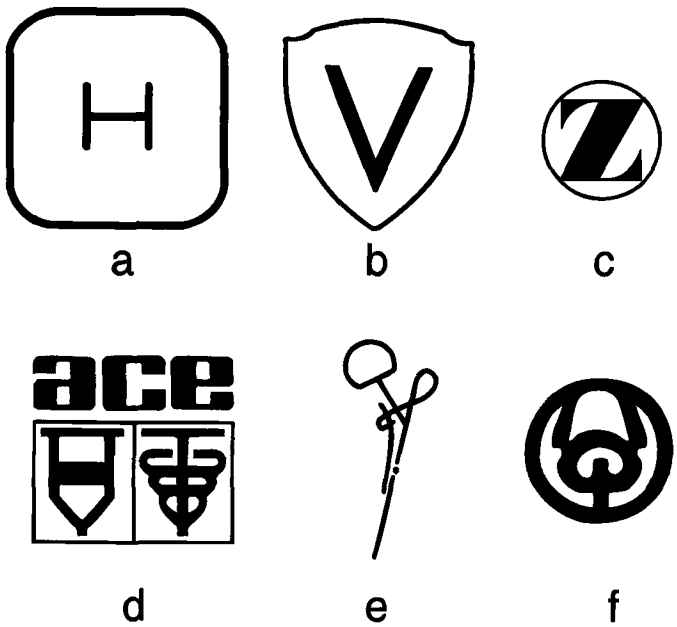

FIG. 1—*Company logos:* a, b *Howmedica, Inc.;* c *Zimmer;* d *Ace Medical;* e *Osteonics;* f *Synthes (USA).*

provided in Table 1. Although some companies did not respond to the survey and are not included, the list provides the contacts needed to trace recovered devices. If the device was produced after March 1, 1993, then it likely can be traced not only to the manufacturer, but also to the individual patient.

Some employees of the manufacturing companies are so familiar with their products and those of their competitors that they can usually identify them simply by recognition. This capability is important since some devices are unmarked or marked in areas that are not readily observed (for example, the posterior surface of a tibial tray or the inside of an acetabular shell).

In some instances, the larger companies (for example, Howmedica or Zimmer) may be able to identify manufacturers of products other than their own. They maintain files to facilitate identification of other company products since as large companies they tend to be implicated in product liability cases.

Like dentures [7], surgically implanted orthopedic devices may contain markings and information that likely will facilitate identification (Fig. 1). The listing of manufacturers and their symbols provided here is not complete but may expedite the investigative process.

References

[1] Murray, K. A. and Rose, J. C., "The Analysis of Cremains: A Case Study Involving the Inappropriate Disposal of Mortuary Remains," *Journal of Forensic Sciences,* Vol. 38, No. 1, January 1993, pp. 98–103.

[2] Huxley, A. K., "Analysis of Ceramic Substrate Found in Cremains," *Journal of Forensic Sciences*, Vol. 39, No. 1, January 1994, pp. 287–288.

[3] Sathyavagiswaran, L., Selser, S. F., Ferguson, E., and Danialzadeh, E., "Using Pacemakers to Identify Decedents," *Journal of Forensic Sciences*, Vol. 37, No. 4, July 1992, p. 955.

[4] Praemer, M. A., Furner, S., and Rice, D. P., "Medical Implants," in *Musculoskeletal Conditions in the United States*, Park Ridge, IL, American Academy of Orthopaedic Surgeons, pp. 127–141.

[5] Ubelaker, D. H., *Human Skeletal Remains: Excavation, Analysis, Interpretation*, second edition. Washington, Taraxacum, 1989.

[6] *Federal Register*, Vol. 57, No. 104, Friday, May 29, 1992, pp. 22966–22969.

[7] Sathyavagiswaran, L., Florentine, B., Taylor, J., and Romero, N., "Identifying 'Does' with Help of Dentures," *Journal of Forensic Sciences*, Vol. 38, No. 5, p. 1018.

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