NATIONAL BUREAU OF STANDARDS REPORT

10 009

FAILURES IN WIRE BASKETS OF URETERAL STONE DISLODGERS

To

Bureau of Medicine/OMR
Food and Drug Administration
Dept. of Health, Education, & Welfare

U.S. DEPARTMENT OF COMMERCE
NATIONAL BUREAU OF STANDARDS

NATIONAL BUREAU OF STANDARDS

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NATIONAL BUREAU OF STANDARDS REPORT

NBS PROJECT

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FAILURES IN WIRE BASKETS OF URETERAL STONE DISLODGERS

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Failures in Wire Baskets of Ureteral Stone Dislodgers

B. W. Christ and C. H. Brady

References: 1. Bureau of Medicine Work Order Number CPF 2624-69(E).

2. Establishment Inspection Report (EIR) on American Cystoscope Makers, Inc., Central File No. 15,982, A.F. Number 11-366, August 15, 1968.

3. Establishment Inspection Report (EIR) on C. R. Bard, Inc., Central File No. 12,754, A.F. Number 23-534, July 8, 1968.

Description of Item:

Twelve Ureteral Stone Dislodgers were submitted under Reference 1 for identifying cause(s) of failure. This item is used by the medical profession for removing kidney stones. The features of a stone dislodger relevant to the purpose of this report appear in Figure 1a. This portion of a stone dislodger consists of:

1) a flexible cable, 20.5 inches long and 0.080-inches diameter (only about 1 1/2 inches of the flexible cable appears in Figure 1a).

2) a connector attached to the leading end of the flexible cable.

3) a "basket" of four fine wires, each about 1 1/2 inches long by 0.016-inches diameter, at the leading end of the flexible cable.

4) a connector which consolidates the four basket wires and provides a threaded joint for a plastic "filiform" tip.

5) a connector at the trailing end of the flexible cable (not shown in this report) for attaching a handle.

Purpose of Investigation:

It is reported[1] that the majority of repair items are returned because of basket failure. Typical stone dislodgers which have failed appear in Figures 1b and 1c. One can see that failure in these cases is a matter of the wire basket having come apart near the connectors. Other failures related to the plastic filiform tip have also been reported[2], but these will not be discussed in this report. The purpose of this report is to identify possible metallurgical causes of the type of failure appearing in Figures 1b and 1c, and to recommend procedures for minimizing the frequency of such failures.

1. Ref. 2, page 4 under heading "GENERAL INFORMATION.

2. Ref. 3, pages 7-8, Items 1-5 under heading "COMPLAINTS".

Material:

Engineering drawings describing ureteral stone dislodgers were available from two different manufacturers (Refs. 2 and 3). These drawings are useful for determining how the item is put together and the materials of which each component is made. The materials used for components near the failed region of the stone dislodger are listed in Table 1. Each manufacturer uses solder to fasten together the flexible cable, basket wires and filiform tip connector. The solder used by each manufacturer is not specified clearly in References 2 and 3.

The materials (and design) used by each manufacturer differ slightly. For example: 1) Manufacturer B specifies a nickel plate finish, presumably for corrosion resistance, whereas Manufacturer A does not, 2) Manufacturer B specifies that the basket wires be type 302 stainless steel with a spring temper*, whereas Manufacturer A specifies type 303 stainless, but no temper condition, 3) Manufacturer B specifies a connector between the flexible cable and the basket wires, whereas Manufacturer A does not. Detailed comparisons of each manufacturer's engineering drawings included in Refs. 2 and 3 will show further slight variations in design and materials. None of these variations would lead one to conclude that one manufacturer's product is better than the other.

General Observations on Usage:

The lifetime of a stone dislodger is variable. An individual stone dislodger may be used repeatedly during a lifetime which can last as long as twenty years. For example, it is reported[3] that the majority of stone dislodgers returned for repair "have been in service for periods up to 20 years". On the other hand, it has been noted that the stone dislodger "is used once or reused at the surgeons discretion".[4]

It is reported[5] that each doctor may change "the shape of the stone basket" prior to use, presumably by bending and twisting the basket wires between his fingers.

When in use, the flexible cable and the basket wires are subjected to both tensile and shear stresses applied through a handle attached to the trailing end of the flexible cable.

When the manufacturer cited in Ref. 2 is supplying a government contract, stone dislodgers are given an autoclaving test which consists of "10/10 minute intervals at 250°F, with sufficient time between to permit

* "Spring temper" is a metallurgical term applied to metal which has been plastically deformed in a fabrication operation, such as wire drawing, in order to increase the hardness and strength of the metal.

3. Ref. 2, page 2 under heading "SUMMARY OF FINDINGS".

4. Ref. 3, Exhibit 6a.

5. Ref. 3, page 6, last paragraph.

cooling to room temperature", and subsequent examination.[6] Presumably, instruments in repeated use are also exposed to similar temperatures in an autoclave.

The manufacturer cited in Ref. 2 gives the solder joints at each end of the wire basket "an acceptability pull test of 40 lbs".[7]

Observations of Fractured Basket Wires and Cross Sections of Soldered Joints:

Examination at magnifications of 10-250 times provides information which serves to identify the possible causes of the typical basket failures appearing in Figures 1b and 1c. For example, Figure 2 shows exterior views at 12X of the soldered joints between basket wires and connectors. Figure 2a shows an intact joint. Figures 2b and 2c show that wires at the filiform connector have fractured. Similarly, Figure 2d shows that wires at the flexible cable connector have fractured. These observations suggest that the cause of wire-basket failure is fracture of the basket wires themselves, and not rupture of the soldered joints.

Views of two fractured basket wires appear in Figures 3 and 4. A view at a magnification of 27X appears in Figures 3a and 4a. Close-up views (at 200X magnification) of the fractured tips of these wires are shown in Figures 3b and 4b. These wires have fractured primarily by shear after a small amount of plastic flow. Evidence of a shear failure is the fact that the fracture surface is inclined to the longitudinal axis of the basket wire. Evidence of plastic flow are the shape distortion of the wires themselves and the rounded features of the fracture surface itself. The cracks penetrating the surface of the basket wire shown in Figures 4b originate in the nickel-plated surface layer. The wire shown in Figure 3b does not exhibit such cracks because the wire was not nickel plated.

When sample surfaces such as those appearing in Figures 3b and 4b are etched with 20% HCl-5% HNO_3, features of the metallurgical structure are revealed. For example, after etching, two failed basket wires appear as in Figures 3c and 4c. The layer of nickel plate and its associated microcracks show up clearly in Figure 4c. It can also be seen in Figure 4c that the microcracks are not restricted to the nickel layer; the microcracks actually propagate into the basket wire itself.

Both Figures 3c and 4c show a typical structure for "spring temper" material, i.e., a fiberous appearance with the fiber direction parallel to the longitudinal axis of the wire. For comparison with Figures 3c and 4c, the fiberous appearance of a basket wire from an unused stone dislodger appears in Figure 5. Shape distortion is also apparent in Figures 3c and 4c. These further observations support the viewpoint that the cause of wire-basket failure is fracture of the basket wires themselves, and not rupture of the soldered joints.

6. Ref. 3, page 6, first paragraph.

7. Ref. 2, Exhibit 6.

To verify this viewpoint, cross-sections of the basket wires embedded in solder within the filiform tip connector were prepared from one unused stone dislodger, Figure 6, and from two used stone dislodgers, Figures 7 and 8. The outlines of the basket wires and the filiform tip connector are obvious in all these figures. Because the three different sections have not been taken at the same level in each stone dislodger, small differences in general appearance are noticeable. These differences are not critical for the purposes of the present analysis, however. The apparent termination of basket wires in cone-shaped tips is also a feature of the sectioning process. As one would suspect, this is due to the fact that all the basket wires do not lie completely parallel to, and in, the plane of the section.

The primary feature to be noted in Figures 6 to 8 is the degree of soundness of the soldered joint. It can be seen in Figure 6, obtained on an unused stone dislodger, that although solder has bridged within the body of the connector and created at least seven small pores, there is still a good deal of solder surrounding the basket wires. The bead of solder on the surface of the filiform tip connector, Figure 6, exhibits no pores and completely surrounds the basket wires.

The used stone dislodger shown in Figure 7 shows the features pointed out in Figure 6. In addition, it shows some separation between the basket wire and the bead of solder on the surface of the filiform tip. The extent of this separation is likely to increase with increased frequency of use of the stone dislodger. The significant point to note in Figure 7, however, is that the basket wire fractured before the separation between wire and solder increased to the point where the wire could pull free of the soldered joint.

The used stone dislodger appearing in Figure 8 shows a filiform tip connector with somewhat different geometry than those connectors appearing in Figures 6 and 7. Furthermore, the central hole in the filiform tip of Figure 8a does not penetrate the full length of the tip, as is the case in Figures 6a and 7a. These small differences in design are also illustrated by comparing Figures 1c and 1b. The sectioned filiform tip in Figure 8a is the same as that appearing in Figure 1c, whereas the tip shown in Figure 7a is the same as that in Figure 1b.

Since the sectioning plane is sharply inclined to the longitudinal axis of the filiform tip shown in Figure 8, the cylindrical central hole is somewhat obscured. Nevertheless, some bridging of the solder in the central hole can be seen. Moreover, some separation between solder and basket wires appears. Only a small bead of solder on the surface of the filiform tip surrounds the basket wires at this point. (Compare the solder bead size in Figure 8a with that appearing in Figures 6a and 7a.) As in Figure 7, the important point to recognize in Figure 8 is that the basket wires distorted and fractured before the soldered joint failed.

Some interesting aspects of the nickel-plated basket wires appear in Figures 9 and 10. A transverse section of an unetched nickel-plated wire shown in Figure 9a reveals a sound, reasonably uniform film of nickel completely surrounding the wire. The average thickness of the nickel film is 0.0004 inches. For comparison, an unplated wire appears in Figure 9b.

Longitudinal views of a used basket wire with its nickel plate flaking off appear in Figure 10. These views are close-ups of the sharply bent wire appearing in Figure 1c. Figure 10a reveals a circumferential crack in the nickel layer. (The threads appearing on either side of the crack in Figure 10a are simply dust particles and have no relationship to the crack.) Views of surfaces at the top of the bend in Figure 10a appear in Figures 10b and 10c. Figure 10b is taken at a slightly different section level than that of Figure 10c. Separation of the nickel layer from the basket wire due to poor bonding is obvious in Figure 10b. The soundness of the stainless steel basket wire beneath the flaking nickel plate is attested to in both Figures 10b and 10c.

Analysis of Wire-Basket Failures:

Evidence presented in the preceding section shows that the cause of the typical wire basket failures shown in Figures 1b and 1c is fracture of individual basket wires, in contrast to the possibility that basket wires are pulling free of the soldered joint. Failure is caused by application of loads beyond the fracture strength of individual wires comprising the basket.

Yield and tensile strengths of the types of stainless steels used for basket wire, as described in Table I, are tabulated in Table II. If a tensile load causes a stress which exceeds the yield strength of a basket wire, shape distortion such as that which appears in the case of the left-hand basket wire in Figure 8a will occur. Loads resulting in stresses which exceed the ultimate tensile stress will cause fracture, as in the case of the right-hand basket wire in Figure 8a.

A tensile load of 10 pounds will produce an average stress of 50,000 lb./in.^{2} in a wire of 0.016-inches diameter. This would correspond to a total load of 40 pounds on the entire stone dislodger, assuming an even distribution of load on the four basket wires. Actually, this assumption is not always valid, since only one or two fractured basket wires are found on any individual failed stone dislodger. Hence, the maximum load figures cited are the most optimistic possible. At any rate, a stress of 50,000 lb./in.^{2} is well below the tensile yield and ultimate tensile strengths appearing in Table II. However, tensile loads between 15 and 60 pounds per basket wire will produce stresses which may be about the same magnitude as the yield strength, depending upon the degree of temper. At such loads, shape distortion will result. Shape distortion usually decreases the wire diameter, which in turn reduces the cross-sectional area (see Figure 8a, left-hand basket wire, for an illustration of this point), and consequently, the load bearing capacity of the wire. During repeated use at stress levels comparable

to the yield strength of the basket wires, the load bearing capacity of an individual stone dislodger successively decreases until even a rather small load at one point in the re-use cycle will produce stress levels greater than the ultimate tensile strength. At this point, fracture of the basket wire will occur.

In addition to the considerations cited above for tensile (axial) loading, one must also recognize that torsion (twist) loading is also applied to the basket wires when in use. The arguments cited for tensile loading are also applicable to torsion loading. In fact, it may be that fracture in torsion is a more frequent mode of failure for basket wires than fracture in tension. This viewpoint is hinted at by the frequency with which basket wires fracture immediately adjacent to one connector or the other. It is at these points of maximum constraint to torsion strain that the torsion stress achieves its maximum amplitude.

The layer of nickel plate applied to one manufacturer's stone dislodger contributes to weakening, and probably to fracture, of basket wires. This is illustrated in Figures 4b and 4c, where it is seen that the nickel plated wire exhibits surface cracks which penetrate the basket wire itself. These cracks act to decrease the effective cross-sectional area of the basket wire, thereby decreasing its load-carrying capacity. The reason that cracks originate in the nickel layer is not known with certainty. One plausible cause is the difference in average coefficients of thermal expansion of stainless steel and nickel, 9.3×10^{-6} in./in.-°F and 7.4×10^{-6} in./in.-°F, respectively. At typical autoclaving temperatures, an 0.016-inch diameter stainless steel wire expands radially about 372×10^{-7} inches, whereas a 0.0004-inch hoop of nickel expands radially about 7.4×10^{-7} inches. Another possible cause of cracks originating in the nickel layer is that the metallurgical structure of the plated layer is inherently brittle. This is sometimes the case for electroplated metals. Since fractures have been reported for both unplated and plated basket wires, cracks originating in the nickel layer cannot be the sole cause of basket wire failure. However, they represent a potential cause of fracture which should be eliminated.

It should be recognized that loss of spring temper by recrystallization and conconcurrent weakening of basket wires may occur during soldering or autoclaving. Whether or not this actually does occur depends upon the temperatures reached by basket wires during these operations. Since the solders used by each manufacturer are not clearly specified, this point cannot be examined in specific detail. However, since most solders melt below 400°F, and since recommended annealing temperatures to promote recrystallization of types 302, 303 and 316 stainless steel are around 1900°F, the probability of significant loss of temper occurring during soldering is negligible. The same conclusion applies to the operation of autoclaving, where temperatures apparently do not exceed 250°F.

In view of the abundant evidence that plastic flow occurs in basket wires, e.g., shape distortions as in Figures 3b, 4b, 7 and 8, it is not likely that metal fatigue is an important contributor to basket wire failure.

Recommended Procedures to Follow in Order to Minimize the Frequency of Wire-Basket Failures:

1. Since the analysis presented in this report shows that cumulative damage to basket wires during re-use eventually leads to fracture, the most obvious recommendation to make is to minimize the re-use of individual stone dislodgers. Ideally, a stone dislodger should have its basket wires replaced after a reasonable number of cycles of use. A definition of what represents "a reasonable number of cycles of use" will have to be provided by individuals having a day-to-day familiarity with the use of stone dislodgers.

2. A detailed specification should be made of the material from which basket wires are made. Stainless steels of the types listed in row 3 of Table II have the strength and corrosion resistance required for use as basket wires. However, it is important to specify the degree of temper, i.e., the strength of the wire, more clearly than it is presently specified in the manufacturers' engineering drawings. Perhaps a more direct specification of the strength of a specific type of stainless steel wire, e.g., "minimum yield strength-225,000 lb/in.^{2}; minimum tensile strength-275,000 lb/in.^{2}", would be a more meaningful specification than "spring temper". Along with such a specification, a statement about the ductility of the wire, i.e., capacity to stretch, would also be appropriate, e.g., "minimum elongation in 2 inches-2%".

3. The diameter of a basket wire determines its load-carrying capacity. For a given diameter, d, tensile stress varies as $1/d^2$, and torsion stress varies as $1/d^3$. Hence, the diameter of the basket wires should be as large as is consistent with the use of the stone dislodger.

4. The nickel-plated layer on stone dislodgers produced by one manufacturer acts as a source of cracks which contribute to the fracture of basket wires. It may be desirable to eliminate the nickel plating operation altogether. Stainless steel has an intrinsic corrosion resistance which makes it unnecessary to apply a nickel layer for corrosion resistance. Elimination of the nickel layer would also avoid the problem of flaking associated with the nickel layer, as shown in Figure 10.

5. Examination for flaking nickel layers on basket wires, and elsewhere, is desirable for stone dislodgers presently in use. This could be accomplished simply by looking at stone dislodgers after each use under a low-power binocular microscope. A magnification of 27X, as in Figure 10a, would be appropriate.

6. Although soldered joints do not seem to be a primary cause of failure, features of the soldered joints noted earlier are worth some discussion:

   a) Maximum mechanical strength of the basket-wire-to-connector joint is achieved if the basket wires pass entirely through the connector, as in Figures 6a and 7a. Purely from the standpoint of maximum achievable mechanical strength, the joints in Figures 6a and 7a have an intrinsically better design than the joint in Figure 8a.

   b) Bridging of solder within the connector, as in Figures 6a, 7a and 8a, should be minimized by applying sufficient flux and heat during the soldering operation.

Table I

Materials For Various Components Near the Failed Region of the Stone Dislodger

Component	Manufacturer B*	Manufacturer A**
flexible cable	stainless steel, type 304	stainless steel, type 316++
flexible cable connector	nickel silver	none used
basket wires	stainless steel, spring temper (type 302+)	stainless steel, type 316+++
filiform tip connectors	nickel silver	stainless steel, type 303

+ Specification of type 302 stainless steel was added to engineering drawing on 9/6/68. Apparently, no type was specified on the drawing prior to that date.

++ Original specification asked for left hand wound cable. This was changed to "right" hand wound at an unspecified date.

+++ Original specification asked for type 303 stainless steel wire. This was changed to type "316" at an unspecified date.

* Manufacturer B: American Cystoscope Makers, Inc.

** Manufacturer A: Greenwald Surgical Co.; produced for C. R. Bard, Inc.

Table II

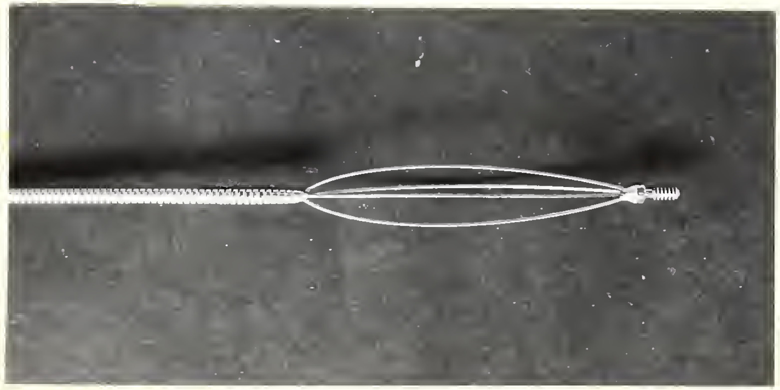
Descriptive Information About Stainless Steel Used For Basket Wires in Stone Dislodgers

Type	Chemical Composition[a] (wt. pct.)				Tensile Yield Strength[b]	Ultimate Tensile Strength[b]	Elongation in 2-inches[b]
	Carbon	Chromium	Nickel	Other	($lb/in.^2$)	($lb/in.^2$)	(pct.)
302	0.15	17-19	8-10		120,000 to 350,000[c]	140,000 to 360,000[c]	15-25 to 1-2[c]
303	0.15	17-19	8-10	0.15 Sulfur, minimum	Not specified	Not specified	Not specified
316	0.15	16-18	10-14	2-3 Molybdenum	100,000 to 260,000[c]	130,000 to 300,000[c]	15-25 to 1-2[c]

a. Metals Handbook, vol. 2, "Properties and Selection of Metals," p. 416, 8th Edition, American Society for Metals, Cleveland, 1961.

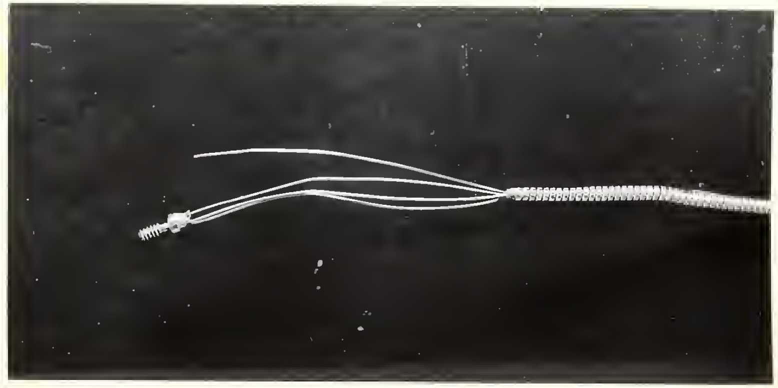
b. "Chromium-Nickel Stainless Steel Data", pp. 16-17, of Bulletin 1A, International Nickel Company, New York.

c. The variations in strength and elongation are due to different degrees of temper. Annealed metal has a low strength in combination with a large elongation. As metal approaches spring temper, strength increases and elongation decreases.



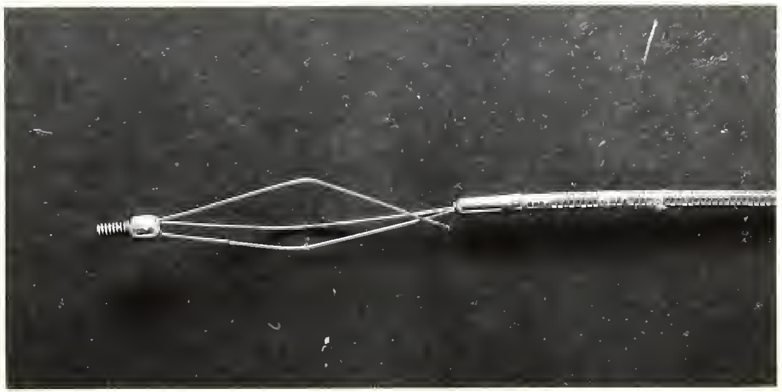
(a) 1X

Unused stone dislodger, showing a portion of the flexible cable, the connector between flexible cable and basket wires, the basket wires, and the connector between basket wires and filiform tip. (Filiform tip is not shown.) Unit produced by Greenwald Surgical Co. for C. R. Bard, Inc.



(b) 1X

Used stone dislodger which has failed. Unit produced by Greenwald Surgical Co. for C. R. Bard, Inc.



(c) 1X

Used stone dislodger which has failed. Unit produced by American Cystoscope Makers, Inc.

Figure 1. Wire-Basket End of Ureteral Stone Dislodgers.

(a) 12X
Filiform tip end of unused stone dislodger shown in Figure 1a.

(b) 12X
Filiform tip end of used stone dislodger shown in Figure 1b.

(c) 12X
Filiform tip end of used stone dislodger shown in Figure 1c.

(d) 12X
Flexible cable end of used stone dislodger shown in Figure 1c.

Figure 2. Exterior Views of Soldered Joints.

(3a) 27X

(3b) 200X

(3c) 250X

Etched in 20% HCl, 5% HNO_3

Figure 3. Tip of Fractured Basket Wire Appearing in Figure lb.

(4a) 27X

(4b) 200X

(4c) 250X

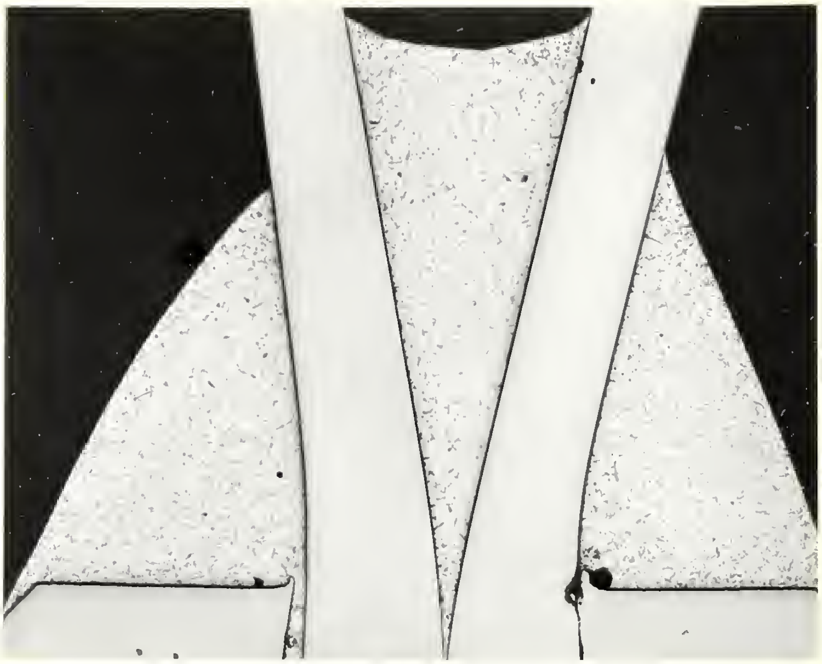
Etched in 20% HCl, 5% HNO_3

Figure 4. Tip of Fractured Basket Wire Appearing in Figure 1c.

250X

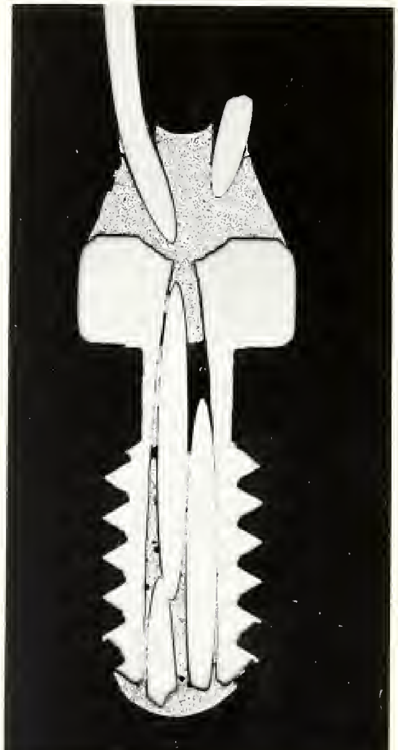
Figure 5. Fiberous appearance of basket wire in spring temper condition. Sample taken from unused stone dislodger appearing in Figure 1a. Etched in 20% HCl, 5% HNO_3.

(6a) 9.5X
Filiform tip and basket wires.



(6b) 50X
Solder bead appearing in Figure 6a at point where basket wires enter filiform tip.

Figure 6. Cross-sectional view of soldered joint within filiform tip. Sample taken from unused stone dislodger appearing in Figure 1a.



(7a) 9.5X
Filiform tip and basket wires.

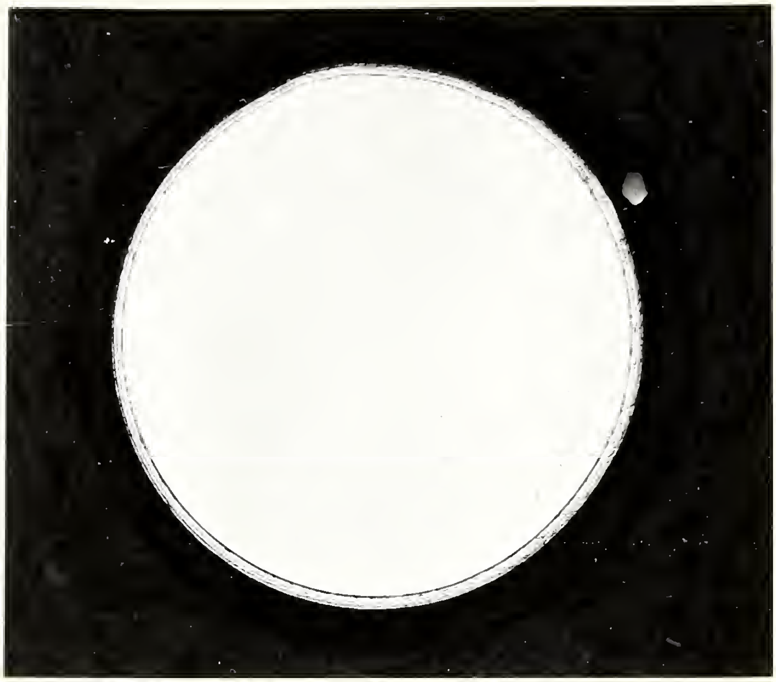
(7b) 50X
Solder bead appearing in Figure 7a at point where wires enter filiform tip.

Figure 7. Cross-sectional view of soldered joint within filiform tip. Sample taken from used stone dislodger appearing in Figure 1b.

(8a) 9.5X
Filiform tip and basket wires.

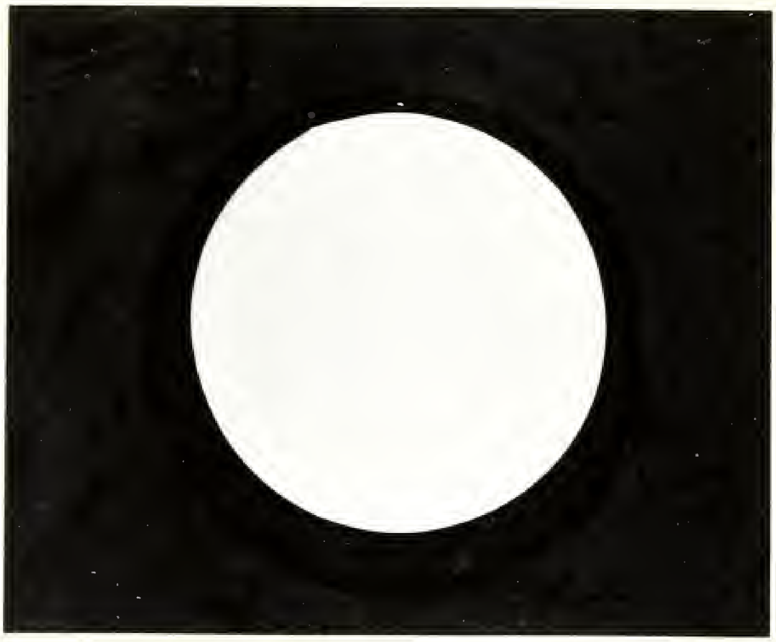
(8b) 50X
Solder bead appearing in Figure 8a at point where basket wires enter filiform tip.

Figure 8. Cross-sectional view of soldered joint within filiform tip. Sample taken from used stone dislodger appearing in Figure 1c.



(9a) 160X

Nickel-plated basket wire. Sample taken from stone dislodger shown in Figure 1c. The nickel layer shows up as the annular ring surrounding the basket wire. Wire diameter-0.016 inches. Thickness of nickel layer-0.0004 inches.

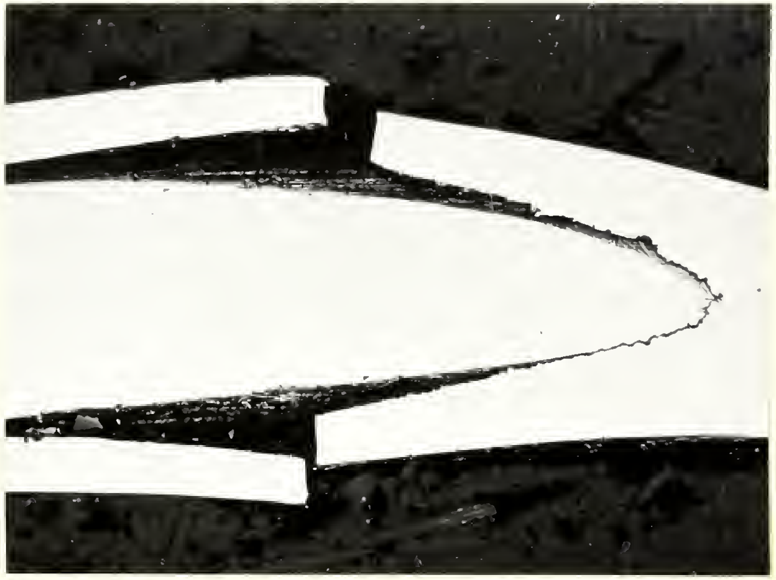


(9b) 160X

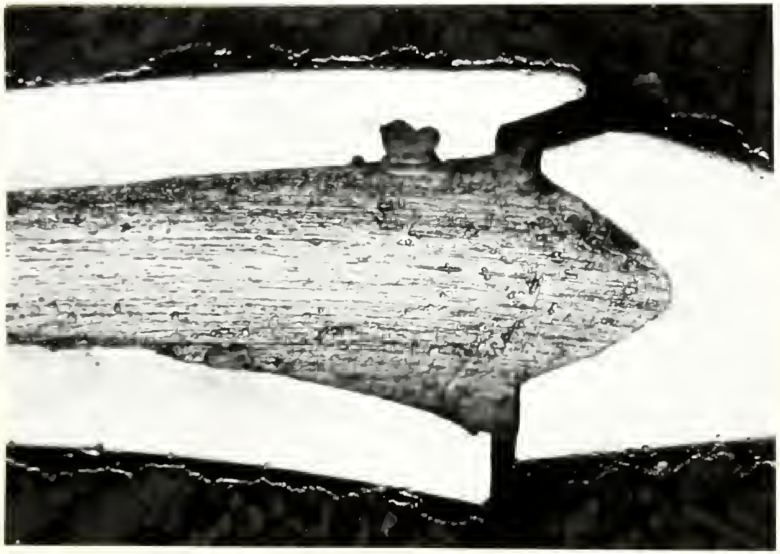
Unplated basket wire. Sample taken from stone dislodger shown in Figure 1b. Wire diameter-0.014 inches.

Figure 9. Transverse Sections of Basket Wires.

(10a) 27X



(10b) 250X
View of top of bend in wire appearing in Figure 10a. Separation of nickel layer from basket wire is evident.



(10c) 250X
View of top of bend in wire appearing in Figure 10a, at a different level than that shown in Figure 10b. Etched in 20% HCl, 5% HNO_3.

Figure 10. Views of Bent Basket Wire Appearing in Figure 1c.

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