MEDICAL DESIGN GUIDE

TO PHOTOCHEMICAL MACHINING
This “Design Guide to Photochemical Machining for Medical Products" was created for those involved with the designing or purchasing of metal parts for healthcare related products. While it provides general guidelines, Fotofab’s technical sales staff is available to assist you with your specific requirements. We understand the unique needs of parts for your application, be it an implantable stent or a nonmagnetic shield. By designing with an awareness of our process capabilities, you will minimize the cost and delivery time of your metal parts. We are ready to work with you. [Just tell us what you need!]

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Fotofab uses a special process called Photochemical Machining. Also known as chemical etching, acid etching, or milling, this process offers many advantages for medical product developers over traditional metal fabrication methods:

**Speed**
- Tooling can be produced rapidly.
- Parts can be produced and shipped within hours of receiving a print.

**Flexibility**
- Many intricate part geometries, like those found in fine resolution screens, can be photochemically machined easily and economically.
- Revisions to part designs are implemented quickly and inexpensively.
- Brittle metals, which often fracture during conventional stamping, are machined without difficulty.

**Repeatability**
- Prototype and production quantities can be made using the same process and tooling.
- Extremely thin metal can be machined without distortion; dimensional accuracy actually increases as metal thickness decreases.
- Physical properties of the metal, such as hardness, strength and formability, are not changed by the process.
- Magnetically soft materials can be fabricated while retaining their optimum permeability.
- Parts are inherently free of burrs.

**Cost Effectiveness**
- Tooling and set-up costs are extremely low compared to hard tooling.
- Our minimum order size is only 2 sheets of parts.
- Part complexity does not impact the part cost.
- Etched logos and part numbers can be added at no cost.
- Parts can be shipped in sheets for easy counting and inventory.

Medical products demand the highest-quality parts.
Fotofab delivers.
**Process**

**Phototooling**
The process begins when we receive your engineering drawing or sketch. We then utilize our CAD system and laser plot technology to generate an image of your part on a set of photographic films, called a Phototool. Depending upon the size of your part, the Phototool may contain from one to several thousand exacting images of your part.

**Coating**
Extremely flat and clean sheets of metal are coated on both sides with a polymer called photoresist that is UV light sensitive and resistant to acids. The coated sheet of metal is vacuum-sealed between the top and bottom layers of the phototool.

**Exposing**
Using the phototool, UV lamps expose the image of your part onto the photoresist.

**Developing**
Developing solution washes away the unexposed coating, leaving a mask in the shape of your part with only the material that is to be etched away left uncoated.

**Etching**
The uncoated areas are etched away, leaving the precisely defined features of your part.
**Stripping**
An alkaline solution is used to remove the mask from the metal surface.

**Forming**
If applicable, forming presses are utilized to bend the etched blank into precise three dimensional shapes.

**Inspection**
Calibrated measuring instruments, including state-of-the-art inspection machines, are used to ensure your part meets your specifications.

In addition to etching, Fotofab offers many of the other manufacturing processes required to deliver a complete part, including:

- Laser cutting
- Wire EDM
- Reaming
- Laser Welding
- Laser Drilling
- Brazing
- Soldering
- Adhesive
- Stamping
- Tumbling
- Heat Treating
- Laser Marking
- Engrave & Fill
- Welding
- Assembly
- Flattening

**Metal Finishing**
- Tin Plating
- Silver Plating
- Black Oxide
- Painting
- Passivation
- Gold Plating
- Nickel Plating
- Black Zinc
- Electropolishing
- Anodizing

Just tell us what you need.
All Fotofab products are custom manufactured to meet your needs. The following products are examples of metal components that we fabricate for medical and other products:
Metals We Etch
Fotofab is capable of etching a wide range of metals. Below is a list of standard metals that Fotofab can etch. If you need to etch a metal that is not on the list, please contact us. We will be able to advise whether or not a specific metal is conducive to the etching process or whether another technique is recommended.

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<tr>
<th>Metals We Etch</th>
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<td>Palladium</td>
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<td>Spring steel</td>
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<td>Titanium</td>
<td>Tungsten</td>
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<td>Tungsten-Copper</td>
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Metal Alloy Temper
Most metal alloys are available in different tempers. In general, the temper specified does not affect the etching process, and whatever temper is selected will remain unchanged throughout the process.

Metal Thickness
Depending on your part design (through etch vs. half etch), Fotofab can produce your part from sheets of metal ranging in thickness from 0.0001 inch (0.0025 mm) up to 0.1250 inch (3.175 mm).

Overall Part Sheet Size
Fotofab typically produces parts from metal sheets that measure 12 inch (305 mm) by 18 inch (457 mm). The overall size of the parts we make can vary from a single part occupying an entire sheet to those yielding several thousand pieces per sheet. Depending on the metal required, the largest part we can manufacture is 24 inches (610 mm) by 36 inches (914 mm). The smallest part that we can make is dependent on the part's geometry and thickness.
The Fotofab Process places no limit on the complexity of your part's configuration. However, there are some limits to the size of the etched features in relation to the thickness of the material. The following are general guidelines for these minimums. If your part requires features that go beyond these parameters, please contact Fotofab to develop a manufacturing solution.

**Hole Size / Slot Width**
Depending on parameters like design layout and metal thickness, the smallest hole diameter or slot width that can be produced by the Fotofab process ranges from 90% – 120% of the metal thickness of a given component. The minimum practical diameter or slot that can be etched is 0.004 inch (0.102 mm).

**Bar Widths**
When a part contains holes and/or slots that are spaced closely together, such as a high resolution screen or encoder disc, the width of the metal that remains between them is referred to as the bar width. The minimum bar width is 0.9 times the metal thickness. The minimum practical bar width that can be machined is 0.003 inch (0.076mm).

**Radii**
In the photochemical machining process, all corners in a part, whether within or along an outside edge, will have an associated radius. The smallest inside radius we recommend for a part design is approximately equal to the metal thickness. The smallest outside radius we recommend is approximately equivalent to 0.9 times the metal thickness.

**Sharp Cornered Objects**
For most applications, basic inside and outside corner radii are suitable. If your design requires a sharp-cornered object to fit into a photochemically machined square hole we can compensate for radii by incorporating corner reliefs as shown in Figure 2.

**Corner Radii of a Narrow Lead**
The Fotofab Process is well suited for making parts with narrow leads. Figure 3 illustrates the radii that will result at the base and end of the lead. If the base area of this lead needs to fit flush against another flat surface, we can compensate for the basic radii by providing the base of the lead with “relief radii” on either side.
**Center to Center Tolerances**
Center to center accuracy is determined photographically, rather than by the etching process. This tolerance is typically considered to be within +/- 0.0005 inches (0.013 mm) over 6 inches (152 mm).

**Etched Dimensional Tolerances**
There are many factors which affect the etched dimensional tolerance including metal type, sheet size, total quantity, and the number of critical dimensions per part. Dimensional tolerances for dropout parts are also different than for parts that remain in the sheet (Refer to the section under “Tabs” for more information). Typical tolerances are as tight as ±10% of the metal thickness.

To provide the tightest tolerances, we recommend that parts be designed to remain within the sheet from which they are etched. This allows for safer handling and easier inventory. The small amount of metal that bridges the part to the sheet is called a tab. Fotofab gives you the option of two different tab designs, depending on the edge requirements of your part.

Figure 4 illustrates the general appearance and maximum tab dimensions of a part held to the sheet by an external tab after it has been removed from the sheet. Figure 5 illustrates the general appearance and maximum tab dimensions of a part held to the sheet by a recessed tab after it has been removed from the sheet. For thicker metal parts, Fotofab can design a small score line etched into one side of either an external or a recessed tab to facilitate the part’s removal from the metal sheet.
If your part’s design cannot accommodate a tab, we can produce the part without any tabs. We refer to an untabbed part as a “dropout” part. A dropout part, however, can be etched less consistently than a tabbed part and therefore has a wider tolerance. Depending on the strength of the metal chosen, typically only a part that is thicker than 0.010 inches (0.254 mm) is a candidate for a dropout part. A Fotofab representative can work with you to select the best option for your part.

**Selective Etching**
Fotofab can selectively etch your part so that any portion of it can end up approximately half the thickness of the original metal sheet. This technique gives you the option to chemically engrave the identification number or a company logo. Another selective etching option allows you to integrate bend (score) lines into your design. Complex screen enclosures and RF shields for surface mount boards are typical applications for this feature. You can even design large portions of your part to be etched to approximately half the thickness of the metal.

Fotofab has manufactured custom RFI/EMI shielding enclosures for decades. If you are considering a shielding enclosure for your project, the following considerations should ensure that your design is as comprehensive and robust as possible. Fotofab will meet your shielding needs from the first prototype quantity to the largest production run, even offering a seamless transition from an etched part to a hard tool when applicable.

**Metal Selection**
Fotofab manufactures RFI/EMI shielding enclosures for attenuating components ranging in operating (and harmonic) frequencies ranging from a few hertz to over 50 GHz. The type of metal that you specify may have an impact on a shield’s performance.

In general, shielding against frequencies of 15 MHz or lower is a bulk material effect, and can best be served by employing a ferromagnetic metal such as steel. For greater attenuation at these lower frequencies, metals with high permeabilities and low core losses such as Permalloy 80 or MuMetal are good candidates.

If the frequencies you are shielding against are greater than 15 MHz, shielding becomes less of a bulk material effect and more of a skin (conductivity) affect. At frequencies (and harmonics) of 900 MHz and above, almost any metal shields similarly assuming a thickness of 0.002” (0.05mm) or greater.

Consider specifying a metal alloy called nickel silver (55% copper; 27% zinc; 18% nickel) for shields that will be hand soldered or re-flow soldered with flux. In these soldering environments, nickel silver is inherently solderable without any plating. Eliminating the post-solder plating will decrease both the cost and lead time of your project. Note that you should consider post-solder plating like bright tin or tin/lead with any soldering processes which do not utilize an active solder fluxing agent.
While Fotofab is capable of making your shield in metal thickness from 0.001” (0.025mm) to 0.060” (1.5mm), the most common metal thickness which offer good shielding and adequate mechanical strength are: 0.008” (0.2mm); 0.010” (0.25mm); 0.012” (0.3mm); 0.015” (0.38mm) and 0.020” (0.5mm).

**Bend Channels**
Hand-foldable, etched bend channels are one of the unique features that Fotofab can incorporate into your RFI/EMI shielding enclosure. In the common metal thickness listed above, our etched bend channels allow anyone to bend the sidewalls of a shield from a 2D blank to a 3D finished shield easily, quickly and precisely.

Incorporating our etched bend channel feature can offer you several benefits. First, since your shielding enclosure can be formed without the need for any traditional forming tooling, you can typically save hundreds of dollars in NRE tooling and several days of delivery lead time for your prototype and production needs. Second, because the etched bend channels exhibit a zero inside radius when formed, you can save space on your board by reducing the clearance necessary between the shield and the components within it. Third, although the etched bend channels are typically intended to create 90º right angle bends, they can also be used to create acute angle bends between 0º and 90º.

Fotofab does not recommend the use of etched bend channels for applications that are load bearing or encounter extended periods of vibration. Since the etched bend channels are created by removing anywhere from 50% to 75% of the original metal thickness, the strength of the metal along these bend channels is affected. For these applications, we recommend forming the shield blanks with our hard forming tools.

**Part Geometry**
The economics of Fotofab’s parts are similar to purchasing PCB’s in that you are purchasing the real estate of the part rather than the features internal to it. Therefore, features such as mouseholes for traces, holes for tuning or heat dissipation, identification for your shield or shielded components and even your company’s logo are effectively free. And, similar to any other custom part from Fotofab, there is no limit to the complexity of your shield’s configuration.

You can also take advantage of our fabrication process to minimize the size of hole features and slots in your shield design, ideal for traces and holes for tuning, cleaning or heat dissipation as small as possible. Please refer to the dimensional capabilities section for the minimum feature sizes.

**Etched Logos and Part Numbers**
If your design would benefit from being identified with its part number, or you want your customer to see your logo etched into your product, this can be incorporated without additional cost, simply specify submitting your design.
Removable Covers
Your shielding design may require that the cover or lid be removed so that the components underneath can be tweaked or replaced and later resealed. We refer to this design as a “removable lid” or “two piece” shield. We are capable of making removable lid shields with several different mechanical locking or mating methods including: 1) mating dimples, 2) mating tabs and slots, 3) friction fits and 4) locking spring fingers. Each of these methods is best suited to different shield designs. Please contact our Technical Sales staff to discuss which method is best for your part.

Internal Walls
Your application may require internal walls or fences that prevent cross talk among different regions or components under a larger, universal shield. Fotofab is experienced in making extremely complex “multicavity” shields to any specifications and can assist you in the design and production of these parts.

Raised or Rounded Features
Your shielding design may require a part to have a unique feature such as a stepped or domed region, or a shield with rounded, rather than squared, edges or corners. This can be achieved by Fotofab using a combination of etching and other metalworking processes.

Forming Options
We can ship your parts with etched bend channels, tabbed into the metal to easily detach and form by hand with etched bend channels, or fully formed by Fotofab, ready for final board assembly.

As medical technology continues to advance Fotofab is committed to helping medical equipment and medical device suppliers keep up with the demand for custom photo etched components. Our custom fabricated stainless steel components can be found in items such as:

- Instruments and blades in autoclave stainless steel
- Filters and sieves for diagnostic and laboratory equipment
- Surgical needle threaders
- Sensor elements for monitoring devices
- MRI systems
- Dental and Orthodontic appliances
- Veterinary instruments
- Short run fabrication of obsolete metal replacement parts

In addition, Fotofab also has the capability to design and produce custom titanium components for implantable devices.

Medical Implantable
Implantable medical devices, such as stents and pacemakers, have special requirements for precision and material selection. Fotofab has the experience to fabricate necessary components, not just of stainless steel, but titanium and exotic metals as well. From your CAD file, we can often produce finished prototype parts in one business day, without the expense of tooling.

- Precision etched metal parts
- Contacts, pins, terminals and connectors
- Springs
- Filters
As a preferred supplier of custom made precision metal parts to hundreds of leaders in the aerospace, defense, medical, telecom, and electronics industries, Fotofab is committed to quality. As part of our commitment to quality, Fotofab holds the following certifications:

**ISO Certifications**
Fotofab is proud to have earned the ISO 9001:2008 certification. The Fotofab team is diligently working on obtaining AS9100 certification. [View certificate.]

**RoHS and REACH Compliant**
Fotofab makes precision metal parts to the specifications of our customers, if the parts are designed as RoHS and REACH compliant, then we make them RoHS and REACH compliant.

**ITAR**
Fotofab is a ITAR registered manufacturer. [View certificate.]

**Conflict-Free Mineral Policy**
Fotofab will assess its supply chain as required to assure Fotofab, LLC adheres to Section 1502 of the 2010 Dodd-Frank Act. It does this by requiring suppliers to submit a completed EICC report.

*Contact Fotofab by phone, email, or at fotofab.com.*