PALMETTO GBA
A CELERIAN GROUP COMPANY

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Application for Code Verification Review

The application is being submitted:

☑ For a new product, not previously coded by PDAC.

☐ For a product previously submitted for review in which the application was rejected. Provide DCN number from rejected application: _____

☐ For a previously reviewed product that has been modified since initial review. Provide DCN number from previous application (if available): _____

☐ For a product previously reviewed by PDAC in which the 45-day timeframe for submitting a reconsideration has lapsed.

Note: This application will now be considered a new application for this product.

Provide DCN Number from previous application: _____

Section A - Manufacturer Information

Manufacturer Name: Anodyne	Manufacturer Point of Contact: Bobby Kanter	
Email Address: bobbyk@anodyneshoes.com	Telephone Number: (844) 637-4637	
Mailing Address: 5050 South 2nd. Street		
City: Milwaukee	State: WI	Zip: 53207
Website Address: www.anodyneshoes.com		
Country: USA		

Correspondence will be sent to the Manufacturer's e-mail address unless indicated below:

☐ Please send correspondence to the e-mail address listed below for Designated Representative in the United States.

The following contact information must be completed by the Designated Representative, if different from the Manufacturer information listed above.

U.S. Designated Representative Name:	Company Name:		
Email Address:	Telephone Number:		
Mailing Address:	City:	State:	Zip:
Website Address:	Country: United States		

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Section B - Product Information

Provide the requested information below to be entered into the Product Classification List (PCL). If additional space is needed, add a supplementary page indicating the corresponding section and question the information relates to.

Product name: No. 6 Custom Accommodative Cork Inserts
Model Number (write "NONE" if there is no model number): No. 6 Custom Accommodative Cork Inserts
Does the product need a PCL Comment for Model Number explanation to clarify size, color, height, etc.? ☐ Yes ☑ No If yes, please provide a comment to be entered into the Product Classification List (PCL). (Example of comment: XX in Model Number indicates size). Comment:
Is a product sample required to be submitted per instructions on PDAC Website? ☑ Yes ☐ No
Is a product sample being submitted with this application? ☑ Yes ☐ No

Product Description and Details

Is this product pre-market? ☑ Yes ☐ No
Is this product for home use? ☑ Yes ☐ No
Provide a detailed and complete description of the product. Include all functional information, beneficiary instructions, and any manufacturing information that supports the requested code(s): See steps 1-9 on attached
List all standard component(s) included in the base product (i.e. power cords, batteries, arm rests, etc.), if applicable: See material section on attached

HCPCS Code(s)

List the HCPCS code(s) requested for the product(s) and a detailed explanation for the code(s) selected. If unsure which HCPCS code(s) to request, write "UNSURE" in HCPCS Code Field. Attach additional pages as necessary.

HCPCS Code	Explanation
A5514	For diabetics only, multiple density insert, made by direct carving with cam technology from a rectified cad model created from a digitized scan of the patient, total contact with patient's foot,
	including arch, base layer minimum of 3/16 inch material of shore a 35 durometer (or higher), includes arch filler and other shaping material, custom fabricated, each

If previously coded by other insurers or agencies, provide the code(s) assigned:

Food and Drug Administration (FDA) Information

Most Current Year of Registration: 2019	Establishment Registration Number: 3011654627	510K Number: Exempt 890.3475

- ☐ FDA Manufacturer Name listed on FDA registration **must** match the manufacturer name listed in Section A
- ☐ A copy or screen shot of the manufacturer's current year FDA Establishment Registration and Device Listing from the FDA's website AND the 510K Number (if applicable) **MUST** be submitted with the application.
- ☐ Enteral Nutrition does not apply.

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Section C: Product Specific Information

Provide the requested product specific information or answer the questions related to the products listed in Section B - Product Information of the Coding Verification Review Application.

Therapeutic Inserts and Shoes

Therapeutic Inserts (prefabricated) for Diabetics:

Is the insert molded directly to the beneficiary's foot immediately following the use of an external heat source (excluding heat sources commonly used as commercial hand-held hair dryers) that can produce heat at temperatures of 230° or greater?	☐ Yes	☐ No
Is the insert molded by use of "compression molding" (molding via the beneficiary's weight and body heat) without the use of an external heat source?	☐ Yes	☐ No
Provide the shore A durometer measurement of the base material (for requested code A5512):		

Therapeutic Inserts (custom fabricated) for Diabetics:

Is the insert molded directly to a physical positive model of the beneficiary's foot?	☐ Yes	☒ No
Is the insert direct carved/milled from a rectified virtual model of the beneficiary's foot?	☒ Yes	☐ No
Provide the shore A durometer measurement of the base material (for requested codes A5513 and K0903):	Minimum 35shore A	

Step-by-step description of the fabrication process **MUST** be provided. Include color photographs of each step within the fabrication process.

Therapeutic Shoes (prefabricated) for Diabetics

Are there 3 or more widths available for the product?	☐ Yes	☐ No
Do the shoes come in half sizes?	☐ Yes	☐ No

Therapeutic Shoes (custom molded) for Diabetics:

Is the shoe molded directly to a positive model of the beneficiary's foot?	☐ Yes	☐ No
Is the shoe made from leather or other suitable material of equal quality?	☐ Yes	☐ No
Does the shoe have removable inserts that can be altered or replaced as the beneficiary's condition warrants?	☐ Yes	☐ No
Does the shoe have some form of closure?	☐ Yes	☐ No

Step-by-step description of the fabrication process **MUST** be provided. Include color photographs of each step within the fabrication process.

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Section C - Product Specific Information

Prior to completing Section C and application submission, review all appropriate DME MAC policy related material (DME MAC LCD, coding and policy articles, etc.).

Locate, complete and attach Section C for the product type being submitted. This appendix can be located on the Applications page. Section C **must** be attached or the application will be rejected.

Prosthesis applications are not required to submit a Section C. Attach any additional documentation and/or photographs to support your requested code.

For Power Mobility Devices, attach a completed PDAC Test Report-for Performance Testing for Power Wheelchairs form. This is located on the Applications page. The form is required and the application will be rejected if not attached.

Section D - Authorized Signature

The certification **must** be signed by a person in one of the following offices: owner, general partner, chief executive officer, president, chief financial officer, chief operating officer, executive vice-president, or a similar title that clearly shows that the signer holds a position of status and authority within the organization comparable to those offices. In the case of a signature by someone lacking any of the foregoing, the signature **must** be accompanied by a copy of a resolution of the organization's board of directors, certified by the organization's secretary, that the organization has authorized the signer to execute the certification.

I certify that the foregoing statements are true and correct and to the best of my personal knowledge. I understand that the information being provided will be used by the U.S. Department of Health and Human Services and its contractors to make decisions that may affect claims payments under the Medicare program. I further understand that if the information provided is untrue, I may be subject to sanctions, including civil money penalties and debarment from federal programs. If I become aware that any information in this application is untrue, incorrect, or incomplete; I agree to notify the PDAC of this fact immediately.

I agree, in order to support correct coding of the subject product, that should there be a change in product name, a change in model number, or any substantial change in design, construction or performance, I will submit relevant information and documentation to the PDAC for consideration within thirty (30) day of such change. I also agree that should there be a change in the submitter identification as set forth in Section A, I will submit the correct information to the PDAC within thirty (30) days of such change. I also agree to submit product information to the PDAC upon the PDAC's request to ensure the continued correct coding of the subject product.

Authorized official name: Bobby Kanter

Authorized official title: CEO

Signature: _____ Date: _____

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search

Back To Search Results

Establishment:
ANODYNE
5050 S 2nd St
Milwaukee , WI 53207
Registration Number: 3011654627
FEI Number*: 3011654627
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2019

Owner/Operator:
Anodyne[6]
5050 S 2nd St
Milwaukee, WI 53207
Owner/Operator Number: 10049577[7]

Official Correspondent:
Brian Oreilly
Anodyne
5050 S 2nd St
Milwaukee, WI 53207
Phone: 1-414-8771951

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/MedicalDevices/default.htm
5. https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10049577&OwnerOperatorN
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10049577&OwnerOperatorN

Page Last Updated: 11/11/2019

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive

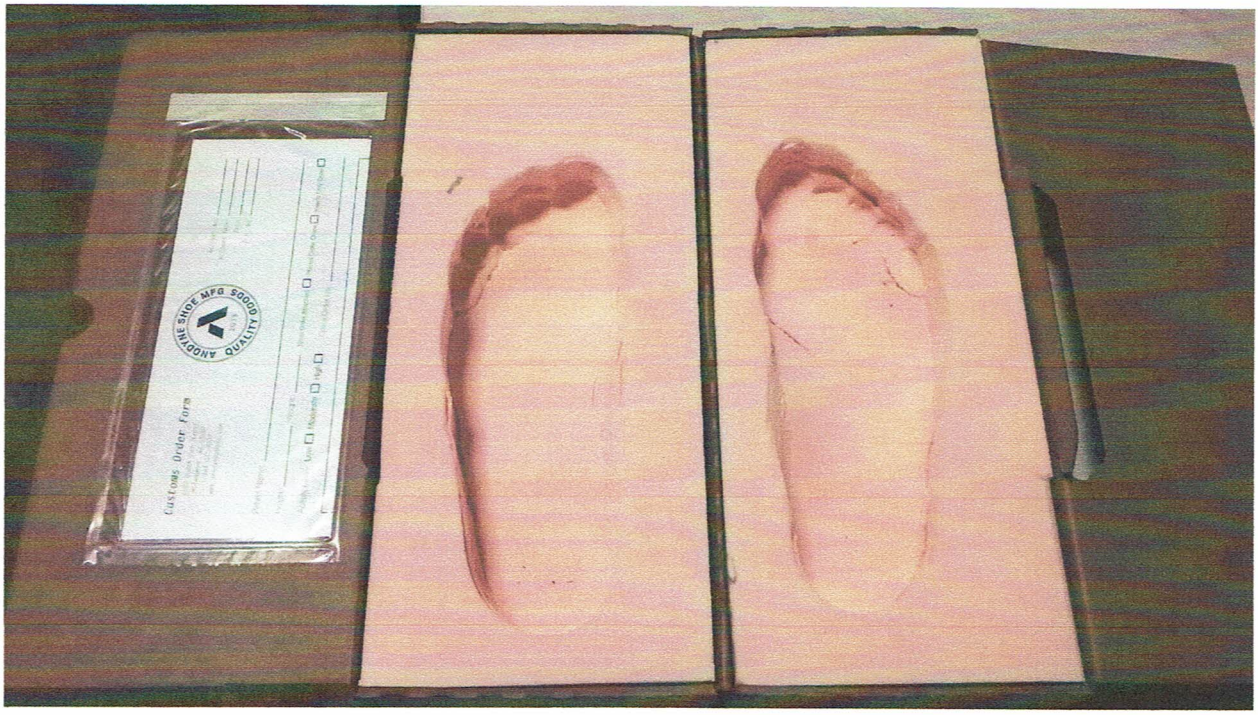
U.S. Department of **Health & Human Services**

Links on this page:

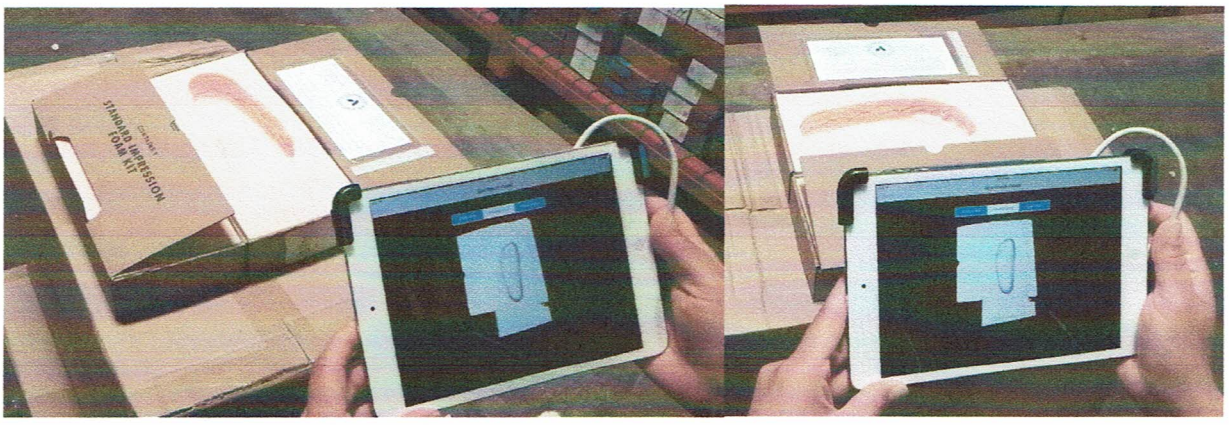
Anodyne – A5514 Fabrication Process –

No. 6 – Custom Accommodative Cork Inserts – Mill

1) We receive an impression of the patients foot from either a) an impression foam box (shown here), or b) a positive scan from a scanning application directly from the provider (a 3-Dimensional .stl file).

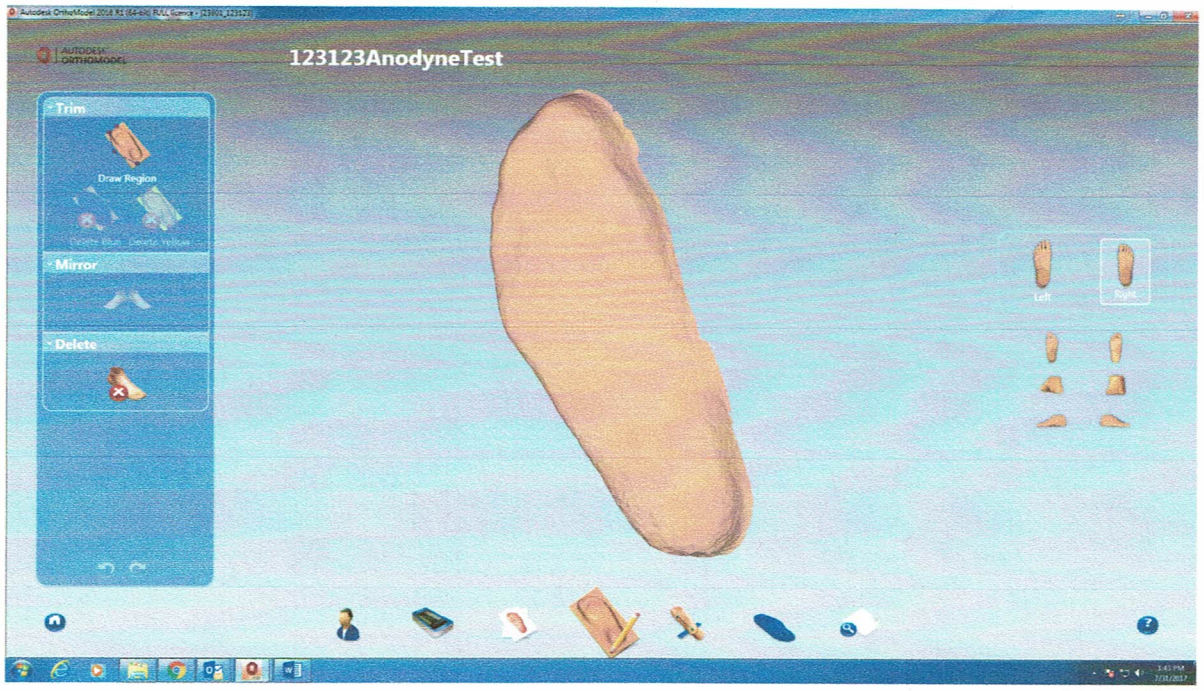


2) We then do a full 360 degree scan of the impression foam, in order to capture a 100% accurate digital image of the foam impression.
   a. We scan the left and right feet separately, and then store those scans in our CAD-CAM system as unique "left" and "right" files.
   b. We DO NOT use mirror imaging. If we receive positive scans from the provider, we require separate scans of both the left and right feet when a full pair of inserts is requested.



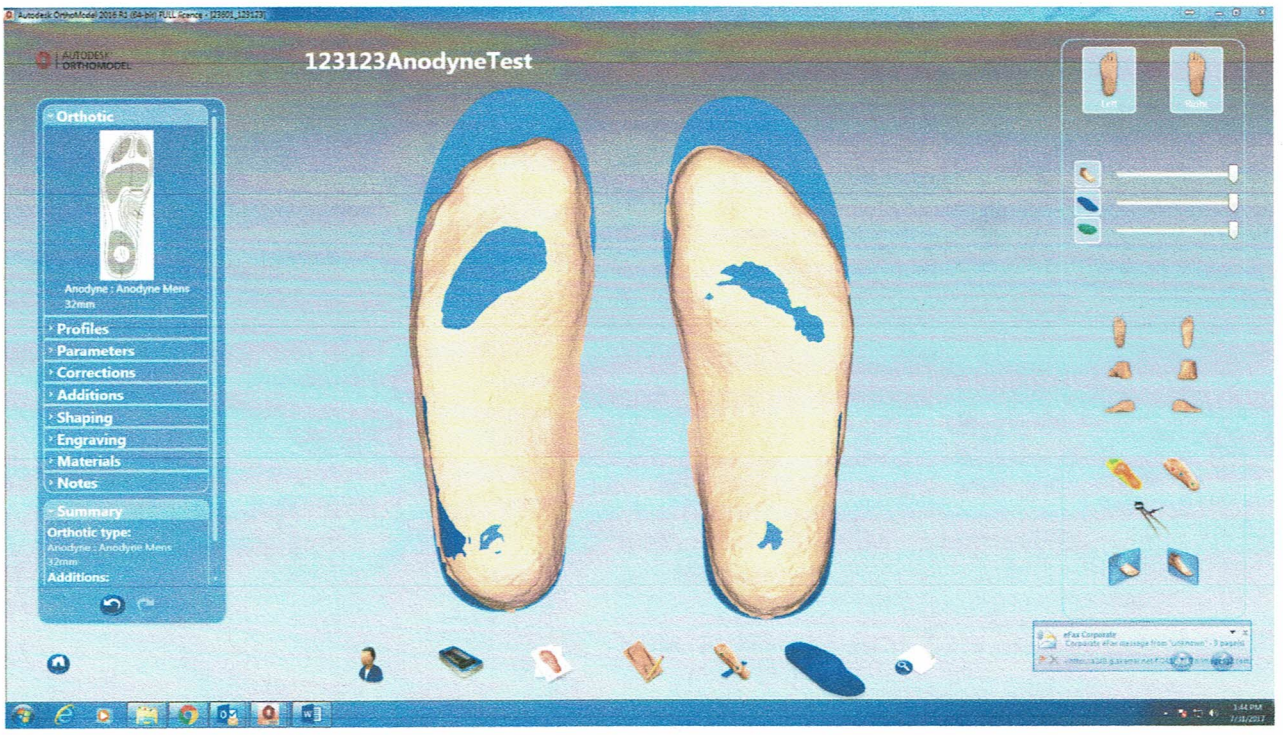
3) The 3-dimensional scan file is then sent and uploaded into an orthotic manufacturing CAD-CAM program and a computerized positive model is created for both the left and right feet.

(Left foot)



(Right foot)

4) The computerized positive model, is then used within our CAD-CAM software, to design and develop full contact, custom inserts that perfectly match the contours of the patient's foot/feet. A full contact, custom design is developed based off the digital, positive model of the patient's feet. Both the left inserts and right inserts are completely unique and designed independently of each other. We DO NOT use a library system and we DO NOT use mirror imaging.


123123AnodyneTest
Orthotic
Anodyne : Anodyne Mens
32mm
Profiles
Parameters
Corrections
Additions
Shaping
Engraving
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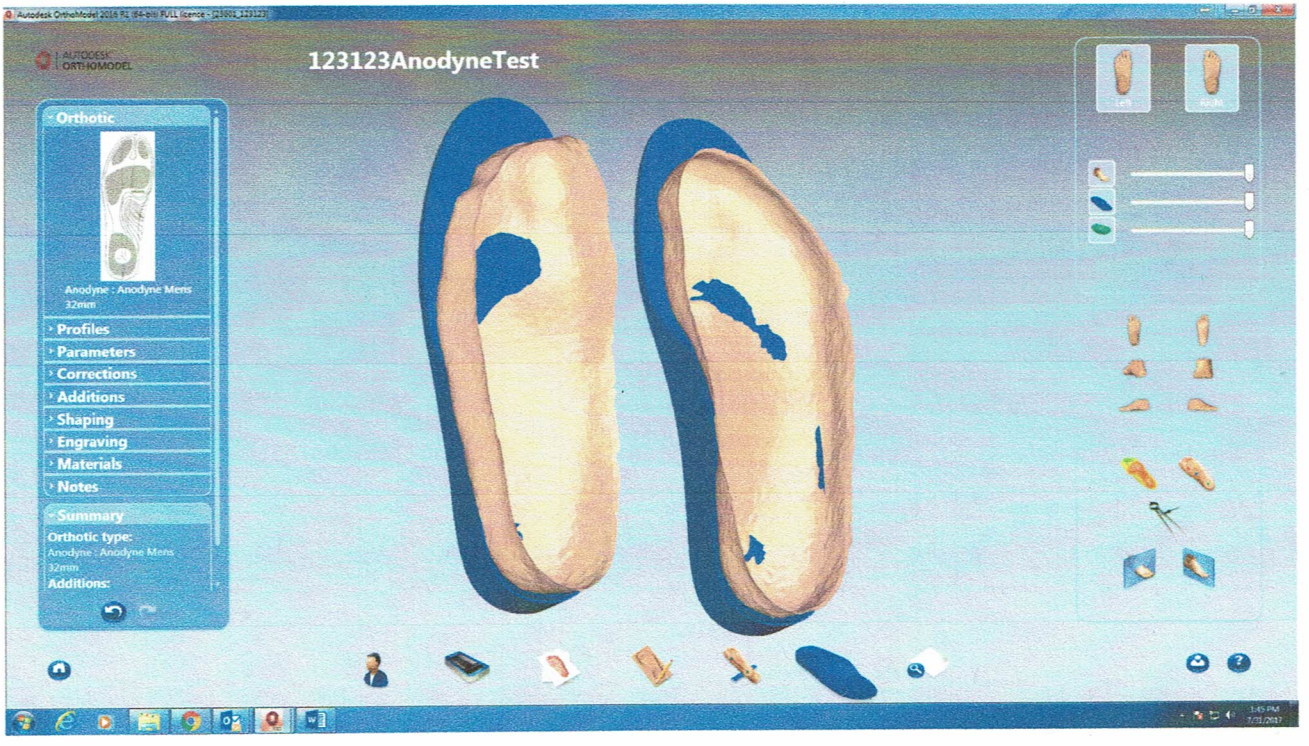
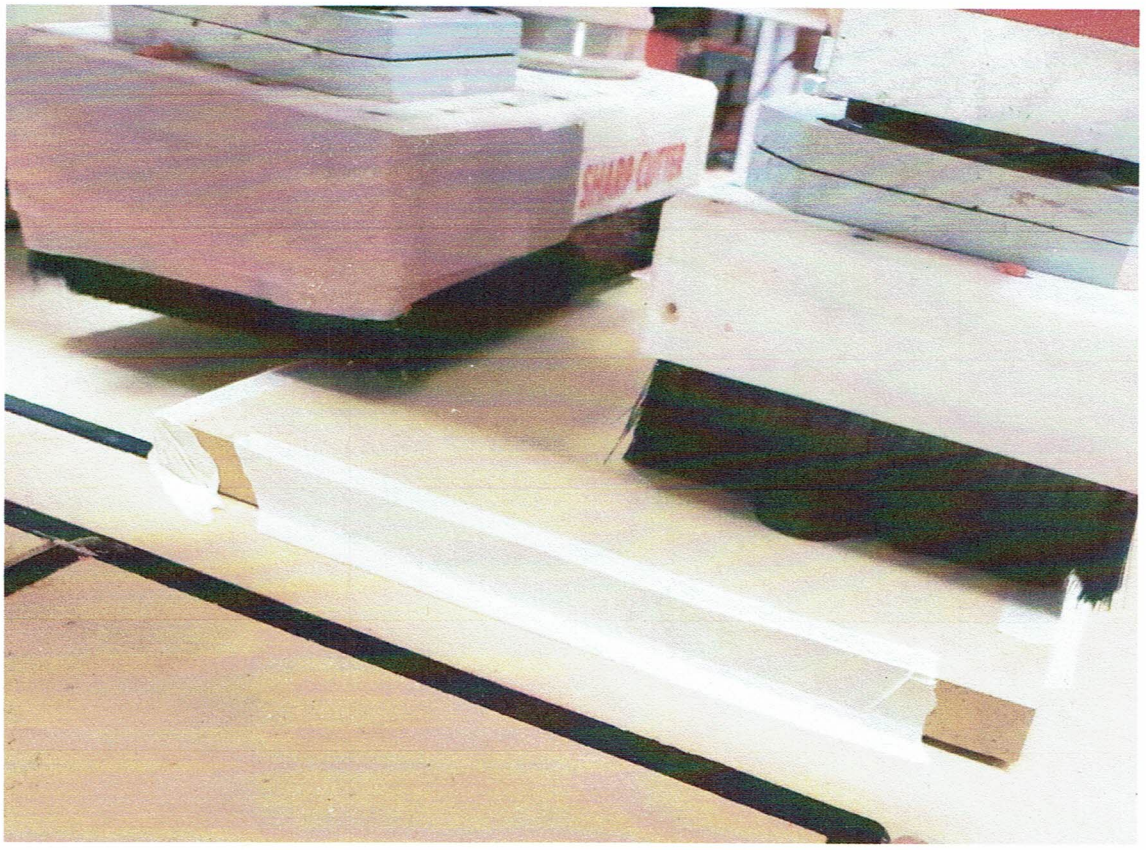
Notes
Summary
Orthotic type:
Anodyne : Anodyne Mens
32mm
Additions:


123123AnodyneTest
Orthotic
Anodyne : Anodyne Mens
32mm
Profiles
Parameters
Corrections
Additions
Shaping
Engraving
Materials
Notes
Summary
Orthotic type:
Anodyne : Anodyne Mens
32mm
Additions:

5) Starting from an unshaped, solid block of EVA (maintaining a durometer of at least 35A), the orthotics designed and developed in the CAD-CAM program, are sent to our CNC machines to be milled.



(Before)

(During)

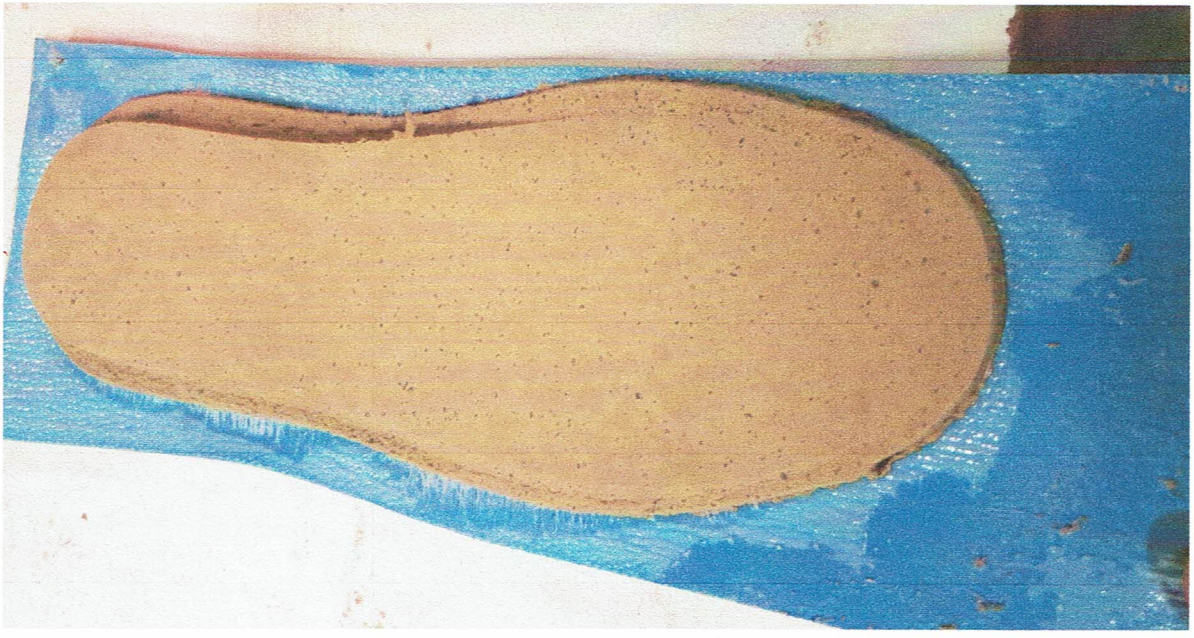
6) After the CNC has finished milling, the inserts are cut out.

(Orthotics cut out of EVA block)

7) After being cut out, a heat moldable Poly Ethylene (PE) top cover is applied to the inserts.

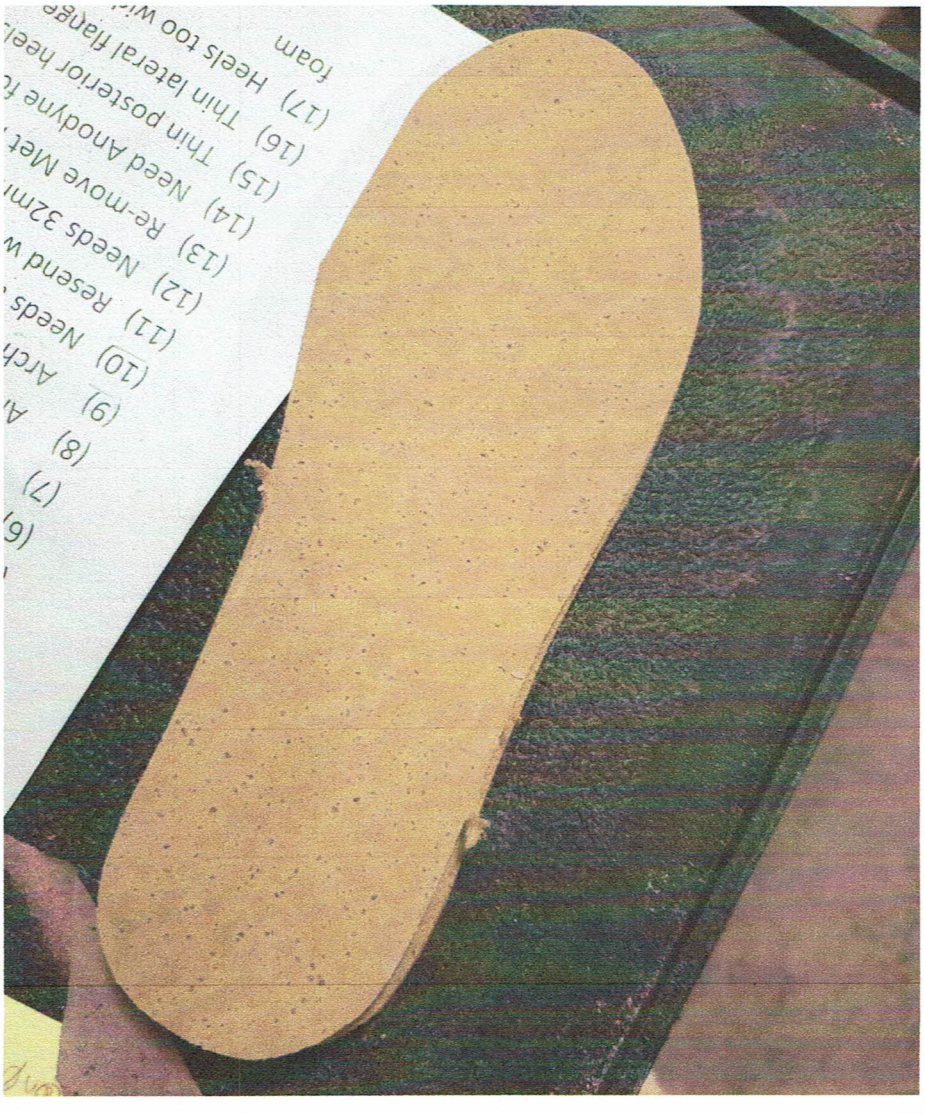
(Glue is applied to top cover and top cover is pressed onto insert)

(Top view)



(Bottom view)

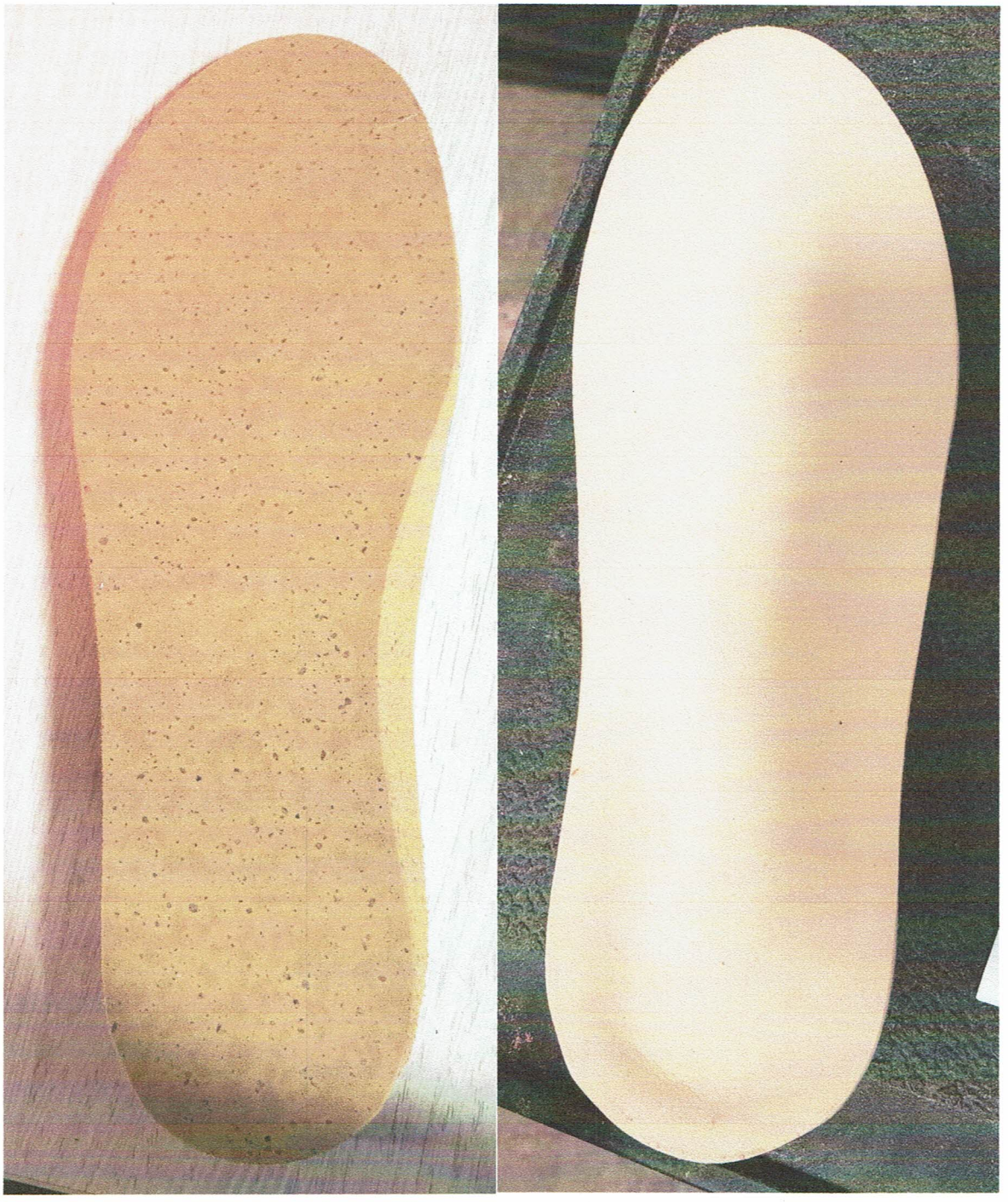
8) Cut top cover down to size



9) Final step is grinding and smoothing the edges and arch of the inserts.

Final Product:

Bottom View



Materials

- 35A+ Cork/EVA Base
- Heat moldable PE Topcover

Features

- Inserts completely conform to the plantar surface and make total contact with the foot, including the arch based on the digital, positive model.
- Base 3/16 inch minimum
- 100% unique, custom product

A5514 Coding Checklist

To be assigned to HCPCS A5514, information must be included showing that the product:

- Is a custom fabricated insert
  - *Yes, inserts are individually made for a specific patient, which is based on clinically derived and rectified castings, tracings, measurements, and/or other images. The fabrication process, as detailed above, begins with the use of uncut and unshaped basic materials and substantial work is done for each individual order (designing, milling, gluing, grinding, etc.).*
- Is a multiple density insert
  - *Yes, two layers – 1) Heat Moldable PE top cover 2) Heat moldable, EVA base with a 35A+ durometer base*
- Is directly milled from a beneficiary-specific, rectified digital (virtual) model
  - *Yes, images of digital, positive model are shown in step 3*
- Is made from basic materials
  - *Yes, raw materials are a rectangular sheet of heat moldable EVA material and rectangular, heat moldable PE top covers*
- Has total contact with beneficiary's foot, including the arch
  - *Yes, inserts make total contact with digital, positive model, as seen in step 4*
- Has a base layer that has a minimum 3/16-inch material of Shore A 35 durometer (The central portion of the heel may not be less than 1/16 inch thick)
  - *Yes*
- Has the specified thickness of the base layer extending from the heel through the distal metatarsals (May be absent at the toes)
  - *Yes*
- Has a heat-moldable top layer
  - *Yes*
- Retains its shape during use for the life of the insert
  - *Yes*