Medtronic evaluated two suppliers to determine if their additive manufacturing process was a suitable replacement for the current method of deep drawing custom pacemaker shields. A heat treatment softened the as-printed fine, brittle microstructure. After heat treatment, 3D Systems shields had a point defect density comparable to the deep drawn samples. After heat treatment, TransMachine shields had a microhardness most like the deep drawn samples. 3D Systems pores had a lower aspect ratio and average pore size (27.3um), with a more predictable pore formation and geometry compared to TransMachine (49.1um).

**Results & Discussion**

**Characterization**

- Shields as deposited had a fine lamellar α + β microstructure.
- XRD peaks confirmed the above microstructure. No other phases were present.

**Heat Treatment Softening**

Heat treatment reduced the FWHM value for both suppliers. As-deposited, 3D Systems had a higher FWHM than TransMachine. After heat treatment, 3D Systems had a lower FWHM than TransMachine and were closest to the deep drawn shields. Shield thickness and location of scan had no effect. 3D Systems shields with additional processing steps have higher FWHM values, likely leading to more brittle shields.

**Porosity Analysis**

- Sharp pore morphology is more likely to lead to crack propagation and part failure.
- 3D Systems have lower aspect ratio, reducing likelihood of fracture initiation. Pores did not form preferentially in certain areas of the shields of either supplier.

**Residual Stress**

Residual stress measurements on two regions of a 3D shield resulted in measurements of -599 MPa and -668 MPa. Both values are more than half the yield strength of Ti-6Al-4V.

**Conclusions**

- XRD and SEM confirmed additively manufactured shields had a lamellar α + β microstructure.
- While heat treatment revealed point defects for both suppliers, the heat treated 3D Systems were most similar to deep drawn shields.
- Heat treatment increased grain size which decreases the Hall-Petch effect on hardness, leading to more ductile shields.
- The Knoop microhardness data agreed with the SEM and XRD data.
- Heat treated TM shields were the only samples below the maximum microhardness of 365 HK.
- 3D Systems pores are large and unpredictable, making bridging a concern.
- As-deposited shields have high residual stress.
- Derived from suppliers, shields do not have desired properties for use in pacemakers.
- The designed heat treatment resulted in more favorable shields that were not all within specification.

**Recommendations**

- 3D Systems
  - Heat treatment to soften and reduce residual stress
- TransMachine
  - Modification of printing parameters to reduce porosity

While the designed heat treatment was effective, a shorter process should be researched.