HUD Patient Information Sheet

**Full study title:** Click here to enter text.

**Physician Name:** Click here to enter text.

**Department:** Click here to enter text.

**HUD Holder:** Click here to enter text.

**What are Humanitarian Use Device Exemptions?** Humanitarian Use Device Exemptions (HDEs) are exemptions provided by the Food and Drug Administration (FDA) to allow the use and marketing of an Investigational Medical Device that is “intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect or are manifested in fewer than 8,000 individuals per year in the United States.”

**Description of the HUD device**: Click here to enter text.

**Device related procedures:** Click here to enter text.

**Risks/Benefit Ratio:** km

**Physician contact information**: Click here to enter text.

**Documentation of Information Sheet receipt**

* Patient Name:\_\_\_\_\_\_\_\_\_\_\_­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_
* Date this information was provided:\_\_\_\_\_\_\_\_\_\_\_­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_
* Name of person who explained this information to patient:\_\_\_\_\_\_\_\_\_\_\_­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_
* Signature of person who explained information to patient:\_\_\_\_\_\_\_\_\_\_\_­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_