



# UNIVERSITY HEALTH SYSTEM

## Investigational Device Information Form

Patient Enrollment Date:  
Estimated Completion Date:

**THIS FORM MUST BE COMPLETELY FILLED OUT AND A COPY MUST BE PLACED IN A CONSPICUOUS SECTION OF THE INPATIENT AND OUTPATIENT MEDICAL RECORD OF EACH PATIENT ENROLLED IN THE STUDY**

Protocol Title:

Investigator:

Office Phone:

Pager Number:

Home Phone:

Study Coordinator/Assistant:

Pager:

Other Emergency  
Contact:

Pager:

Authorized Prescribers:

Study Duration: From                      To

Expected Total Enrollment: Out-Pt    In-Pt

Name, Model, Manufacturer:

IDE Number:

Who will pay for this device:

\*HCPCS Code:

Indication (s):

Additional equipment/supplies required for use:

Device applied/operated by (check all that apply):

Device applied/operated in the following facilities:

M.D.  Study Nurse  Unit Nurse

Risk Assessment:

Minimal  Non-significant  Significant

If less than significant, who determined level of risk  
(FDA, IRB, etc)?

Is this device FDA approved? Y  N

Is this device an FDA approved investigational  
Device Exception? Y  N

If Yes (Y) Please check one that applies

a) Medicare won't pay but will pay for routine  
procedures associated

b) Approved through Medicare/Trailblazer but need  
paperwork

Specific Risks:	Side Effects(in order of incidence):	
Appropriate Response to Side Effects:  (Immediately contact the Investigator or member of the Research Team)	Adverse Reactions:	
Appropriate Response to Adverse Reactions:  (Immediately contact the Investigator or member of the Research Team)		
Special Instructions:		
Please explain the process on tracking this device:		
<b>NURSING STAFF ONLY: Please sign and date below (or electronically sign and date on emtek) indicating you have reviewed the above information prior to using the investigational device.</b>		

\*(HCPS) Health Care Common Procedure Coding System, Medicare creates these codes (5 digits) to describe items on the bill so everyone knows specifically what is being billed.