Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

Adverse Event Terminology for Medical Device

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Agenda

Global Harmonization Working Party
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- Background
- AET in China
- Application of Terminology

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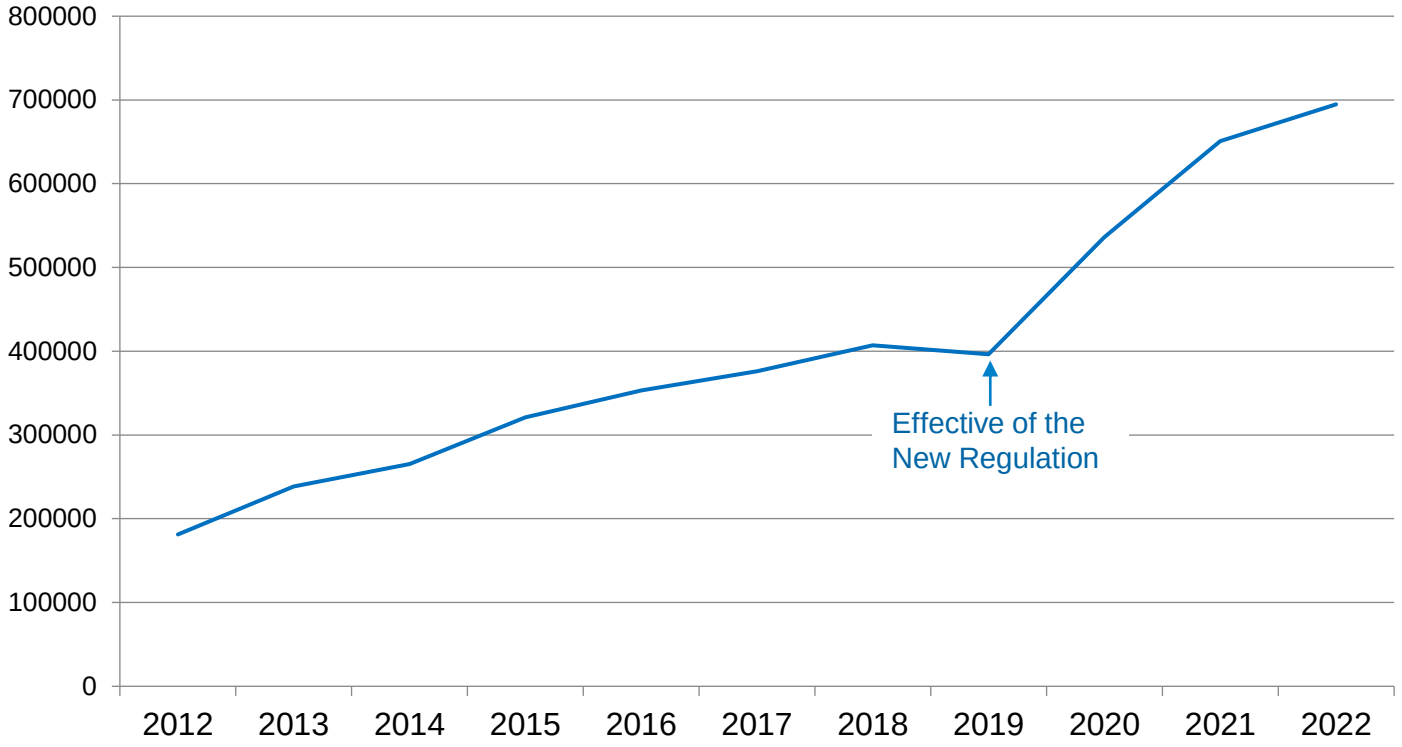
Increasing Volume of AE Reports



Why Is The Terminology So Important?

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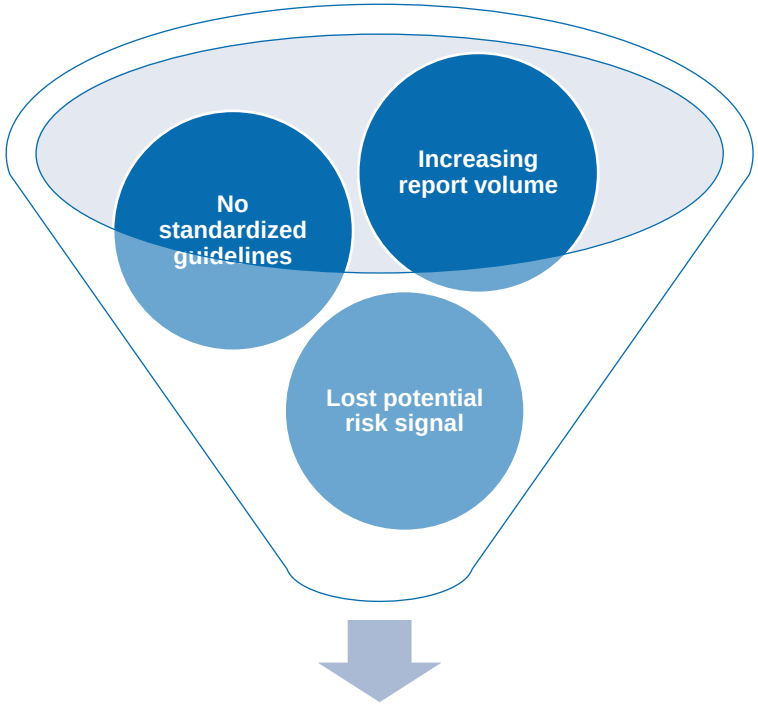

Adverse Event Terminology is required to standardize the report

References

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FDA

JAPAN

ISO

Code Types

The FDA MDR adverse event codes are divided into the following six categories:

Name	Purpose
Device Problem Code	Describe device failures or issues related to the device during the reported event through observational language
Manufacturer Evaluation Method Code	Describe the method of investigation of the device involved in the reported event
Manufacturer Evaluation Result Code	Describe specific findings from the investigation of the device involved in the reported event, typically an explanation for the device problem observed
Manufacturer Evaluation Conclusion Code	Describe conclusions from the investigation of the device involved in the reported event, typically a root cause for the device problem observed
Patient Problem Code	Describe actual adverse effects on a patient that may be related to the device problem observed during the reported event
Device Component Code	Describe specific device components or assemblies associated with the device problem observed during the reported event

ICS › 03 › 03.120 › 03.120.10

ISO/TS 19218-1:2011

Medical devices — Hierarchical coding structure for adverse events — Part 1: Event-type codes

References- IMDRF Terminology

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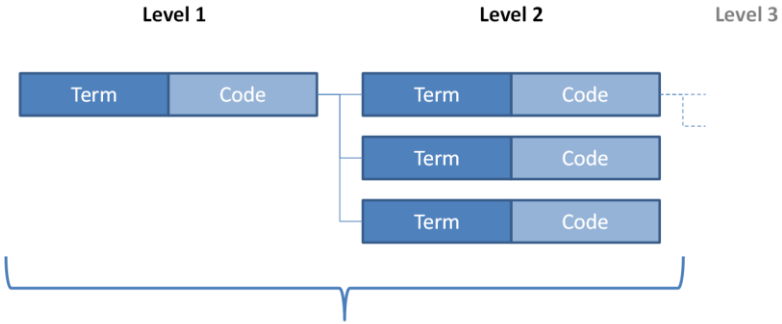
IMDRF International Medical Device Regulators Forum

Adverse Event Terminology

Harmonize terminology for reporting adverse events related to medical devices, and further harmonize adverse event reporting datasets to improve signal detection.



Coding =	The act of assigning a alphanumerical code to a term
Terminology =	Totality of terms used
Hierarchical Coding Structure =	Arrangement of terms in a hierarchical (logical tree-like) structure with various "levels"

Figure 1: *Schematic summary of relevant keywords with respect to adverse event terms: "term", "terminology", "code", "coding", "hierarchical coding structure" and associated "levels".*

Four Sets of IMDRF Terminologies

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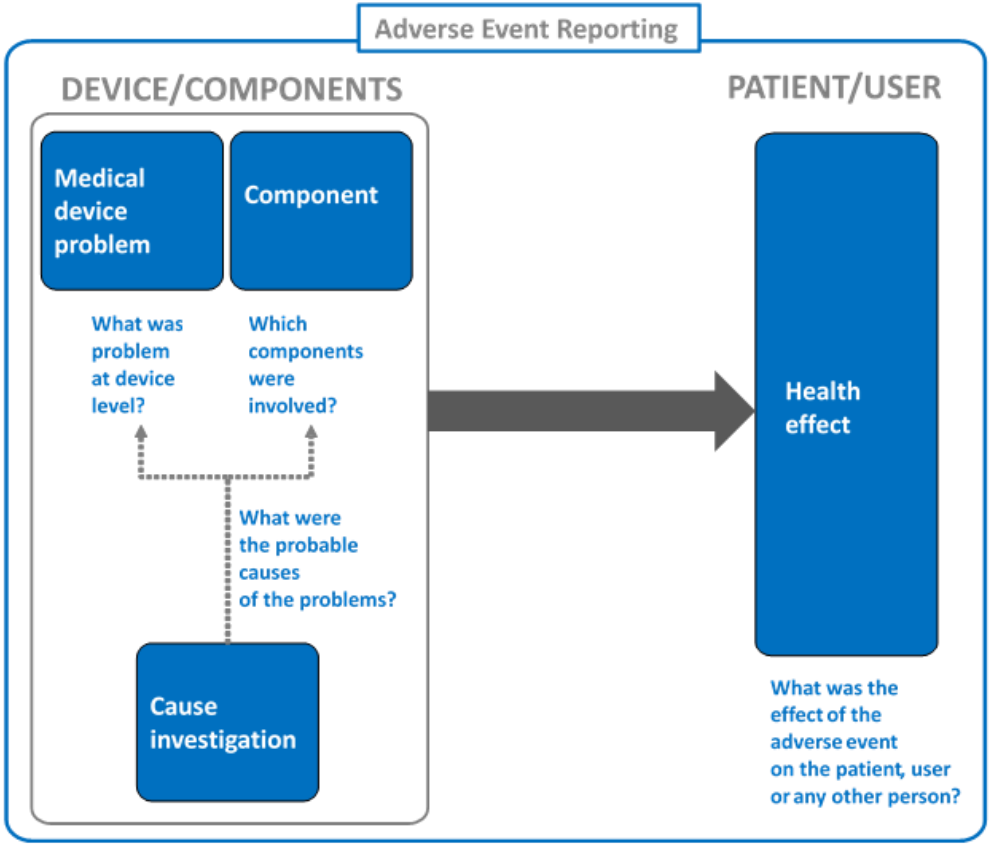

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上市许可持有人医疗器械不良事件报告表

产品名称：腔镜关节头直线型切割吻合器和钉仓

注册证编号：

型号：　　规格：

产地：进口
管理类别：III类
产品类别：无源

产品批号：不详
产品编号：不详
UDI：不详

生产日期：　　有效期至：

上市许可持有人名称：

2

事

事　　6

伤害：严重伤害

伤害表现：血管断端出血

姓名：　　出生日期：

年龄：　　性别：

病历号：不详

既往病史：不详

器械故障表现：击发后钳口自动打开且未成钉

Patient Harm

Malfunction

Basic Framework of Terminology

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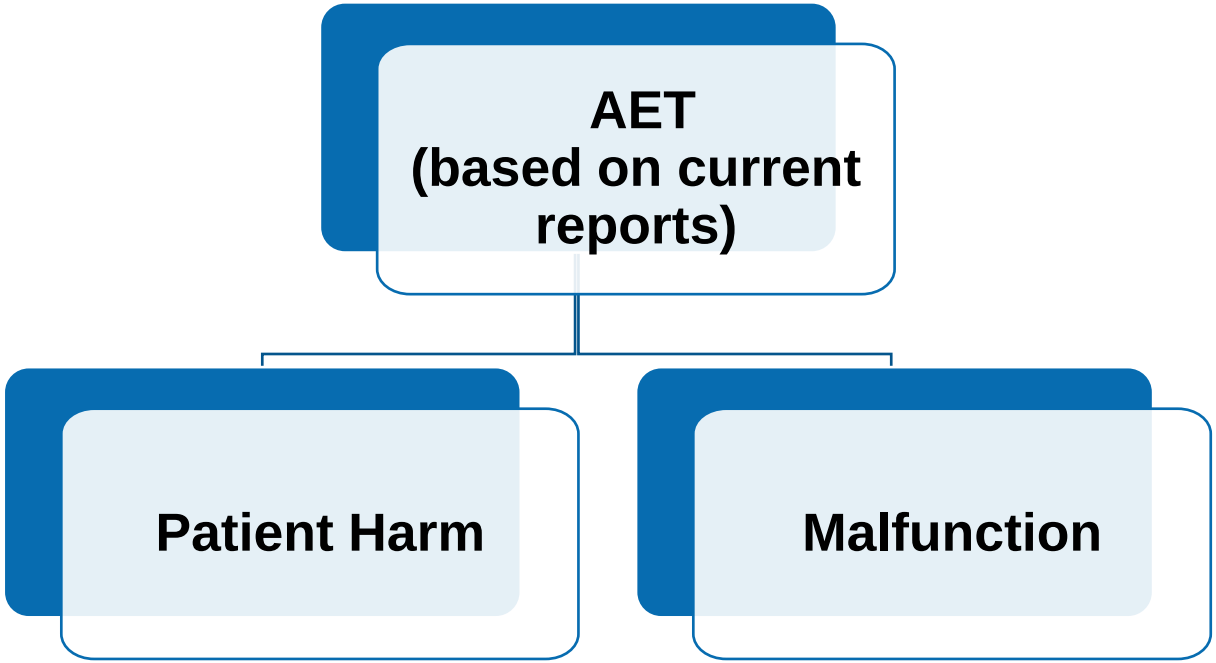

Example- Main Term for Patient Harm

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Code	Terminology (Chinese)	Terminology (English)	ICD code
	3 骨骼、肌肉		
M030100	骨折	Fracture(s)	ICD-10 T14.2
M030101	手臂骨折	Arm fracture	ICD-10 S42.3
M030102	腕部骨折	Wrist fracture	
M030103	骨折延期愈合	Delayed union of fracture	
M030104	髋骨折	Hip fracture	ICD-10S72.0
M030200	骨损伤	Bone injury	ICD-10)13.9
M030201	脊髓损伤	Spinal cord injury	ICD-10 T09.3

Level：3

Coding Structure：M XX XX XX

Example- Hierarchical Term Structure

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故障编码	层级结构术语（中文）	层级结构术语（英文）
	I II/III	
	I. 操作运行问题	Device Operational Problem
D01	操作运行异常	Device Operates Differently than Expected
D0101	故障显示	Fault Display and Message
D0102	意外停机	Unexpected /Accidental shutdown.
D0103	运行失效	Operational Failure
D010301	操作失效	Device Inoperable
D010302	按键故障	Keyboard and Button Failure
D0104	获取样本失效	Failure to Obtain Samples

	II.物理化学性质问题	Physical and chemical properties Problem
D10	电性质问题	Electrical Problem
D1001	采集捕获问题	Capturing Problem
D100101	采集捕获失效	Failure to Capture
D100102	高捕获阈值	High Capture Threshold
D100103	断续捕获	Intermittent Capture
D100104	捕获阈值不稳	Unstable Capture Threshold
D1002	连续触发	Continuous Firing
D100201	频繁误放电	Frequent incorrect discharge
D1003	设备传感问题	Device Sensing Problem

	III. 计算机系统问题	Computer(OS and Hardware) and Software
D17	计算机软件问题	Computer Software Problem
D1701	应用网络问题	Application Network Problem
D1702	应用程序问题	Application Program Problem
D170201	应用程序冻结或失灵	Application Program Freezes，Becames nonfunctional
D170202	应用程序意外中止	Unintended Application Program Shut Down
D170203	程控问题	Programming Problem
D1703	程序计算不正确	Incorrect Software Programming Calculation
D170301	剂量计算错误	Dose Calculation Error due to Software Problem
D170302	参数计算错误	Parameter Calculation Error due to Software Problem
D170303	功率计算错误	Power Calculation Error due to Software Problem
D170304	给药错误	Medication Error

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Terminology Categorization

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Terms for Respiratory System

编码	伤害术语	英文
M060100	肺损伤	Pulmonary injuery
M060200	气管损伤	Trachea injury
M060300	气道阻塞	Airway obstruction
M060301	气道阻力增加	Increased airway resistance
M060400	呼吸困难	Dyspnea
M060500	过度通气	Hyperventilation
M060600	通气不足	Hypoventilation
M060700	呼吸暂停	Apnea
M060800	支气管痉挛	Bronchospasm
M060900	支气管炎	Bronchitis
M061000	哮喘	Asthma
M061100	低氧	Hypoxia
M061200	缺氧症	Anoxia
M061300	窒息	Asphyxia
M061400	上呼吸道感染	Upper respiratory tract infection
M061500	肺炎	Pneumonia
M061501	支气管肺炎	Bronchopneumonia
M061600	肺水肿	Pulmonary edema
M061700	肺叶膨胀	Lung overinflation
M061800	呼吸速率减慢	Decreased respiratory rate
M061900	呼吸速率增加	Increased respiratory rate
M062000	呼吸功能不全	Respiratory insufficiency
M062100	呼吸窘迫	Respiratory distress
M062200	呼吸衰竭	Respiratory failure
……	……	……

Harms of Ventilator

编码	伤害术语	英文
M020114	粘膜损伤	Mucosal injury
M141100	喉损伤	Larynx injuries
M060200	气管损伤	Trachea injury
M020116	气压伤	Barotraumas
M023900	气胸	Pneumothorax
M022300	麻痹	Paralysis
M033100	四肢瘫痪	Quadriplegia
M040100	脑损伤	Brain injury
M052100	高血压	Hypertension
M060600	通气不足	Hypoventilation
M061300	窒息	Asphyxia
M061500	肺炎	Pneumonia
M171301	氧中毒	Oxygen toxicity
M090500	感染	Infection
M170102	心源性休克	Cardiogenic shock
M170400	呼吸性酸中毒	Respiratory acidosis
M060300	气道阻塞	Airway obstruction
M197203	气肿	Emphysema
M020109	切割伤	Incised wound
M061700	肺叶膨胀	Lung over inflation
M023100	瘘	Fistula
M212000	呼吸机依赖	Ventilator dependent
M052400	血压下降	Blood pressure decreased
M180400	触电	Electrocution

System Demo

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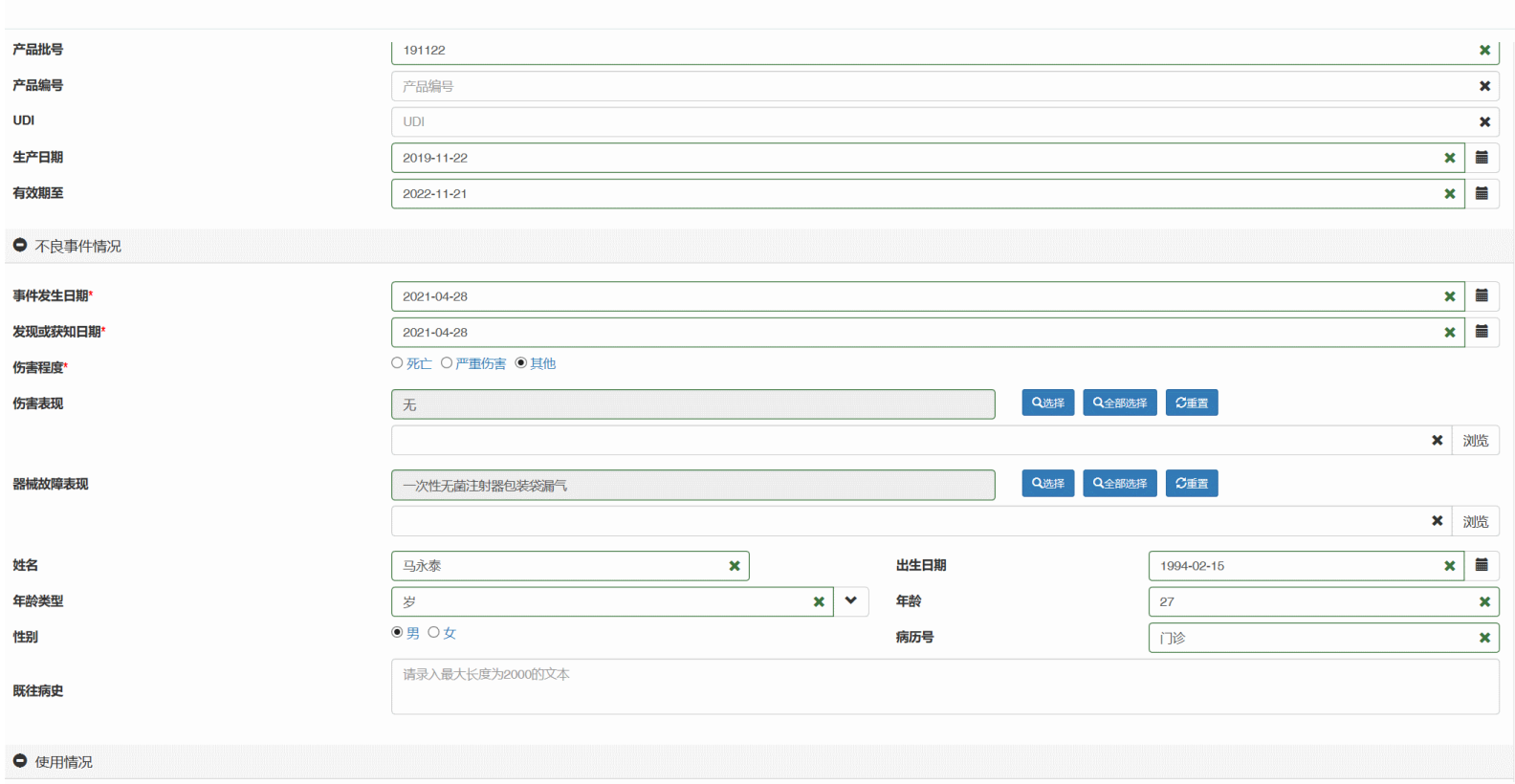

Maintenance and Updates

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Terms for Transvaginal Mesh(TVM)

1	Nervous System	Peripheral Nervous Injury	
2	Vascular System	Hematoma	
3		Hemorrhage/Blood Loss/Bleeding	
4	Gastrointestinal System	Bowel Perforation	
5		Constipation	
6		Melena	
7	Kidney and Urinary Tract	Dysuria	
8		Hematuria	
9		Micturition Urgency	
10		Urethral Stenosis/Stricture	
11		Urinary Frequency	
12		Urinary Retention	
13		Urinary Tract Infection	
14	Reproductive System and Breast	Abnormal Vaginal Discharge	
15		Dyspareunia	
16		Genital Bleeding	
17		Rectovaginal Fistula	
18		Vesicovaginal Fistula	
19		Vaginal Mucosa Damage	
20	Musculoskeletal System	Myalgia	
21	Skin and Subcutaneous Tissue	Impaired Healing	
22		Skin Inflammation/ Irritation	Abscess
23	Infections	Urinary Tract Infection	
24			Abscess
25		Bacterial Infection	Pyogenic Infection
26		Post Operative Wound Infection	
27	Injury	Erosion	
28		Foreign Body In Patient	

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THANK YOU