



Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

Application Practice of UDI in Clinical Use of Medical Devices

Donglan Yu

The First Affiliated Hospital, Sun Yat-sen University



→ *2nd largest Healthcare System in China*



1st Affiliated Hospital
-- largest and leading



Sun Yat-sen Memorial Hospital
-- 1st western hospital



3rd Affiliated Hospital
-- Hepatology



5th Affiliated Hospital
-- Zhu Hai



6th Affiliated Hospital
-- Gastroenterology



Cancer Center
-- Top 3 cancer center



Ophthalmic Center
-- Center of Asia-Pacific
Academy of Ophthalmology



Hospital of Stomatology
-- leader in oral &
maxillofacial surgery



7th Affiliated Hospital
-- the youngest,
Shen Zhen



8th Affiliated Hospital
-- Shen Zhen



One of the Leaders in Medicine in China



Global Harmonization Working Party
Towards Medical Device Harmonization

National Performance Evaluation

A++

**Top 1%
1st in South China**

National Key Specialties

32 (3rd in China)

**1st in South
China**

Fudan Hospital Ranking

**Ranked No. 9
Top 10 Specialties (14)**

**Top 1%
1st in South China**

Annual OPD patients >4.5million, OR >140,000

One of the Best Hospitals in China

National Medical Center in South China
One of 12 Pilot Hospitals for the High-Quality Development of Public Hospitals

Guizhou Division



Headquarter



Huangpu Division



Guangxi Division



Nansha Division





Lean Management of Medical devices



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Lean Management
of Medical Devices

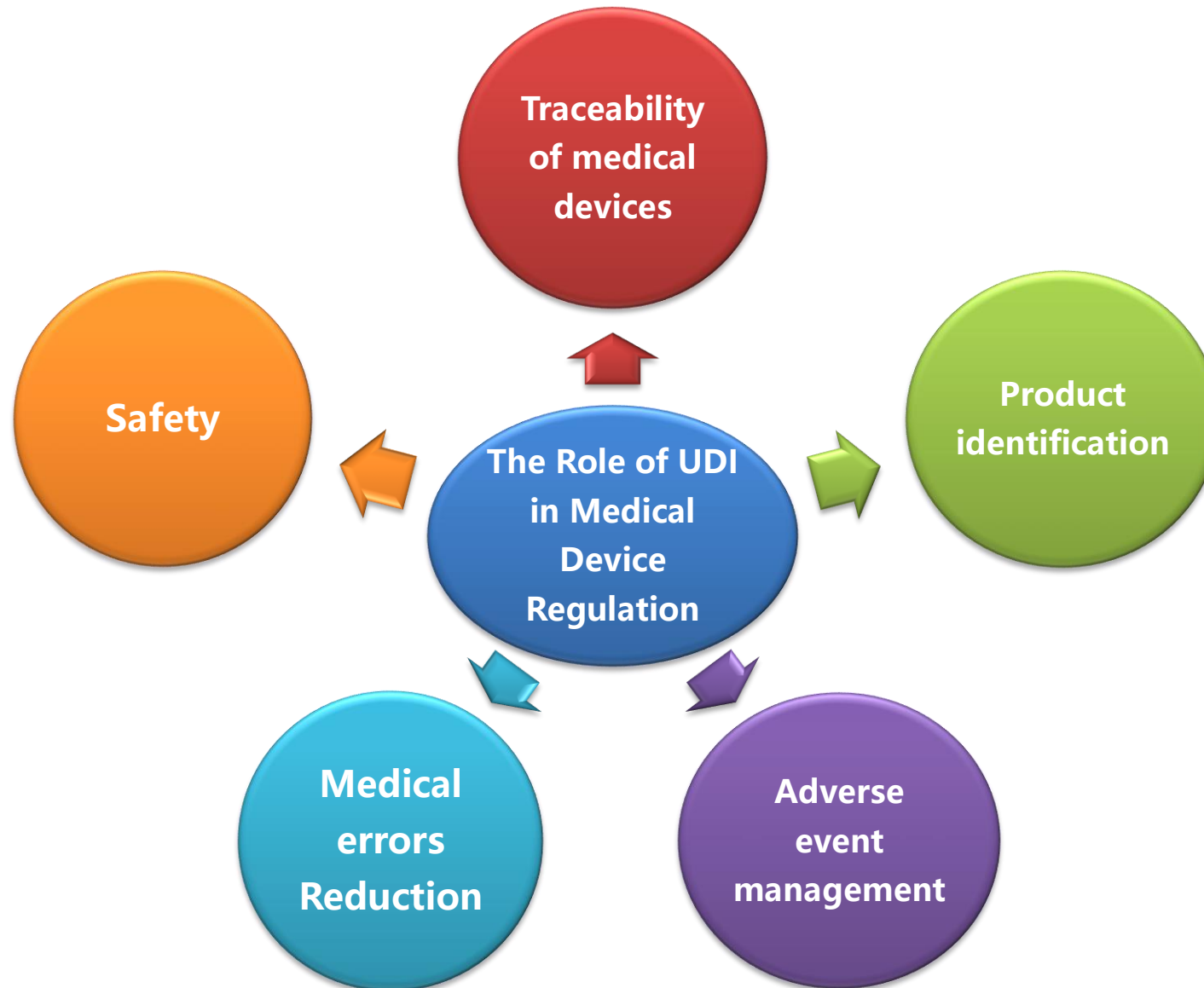
Information Technology and Intelligent
Technology Assistance

Establishment of UDI System
(2011)

One of the First Pilot Users of UDI System in the Country (2019)

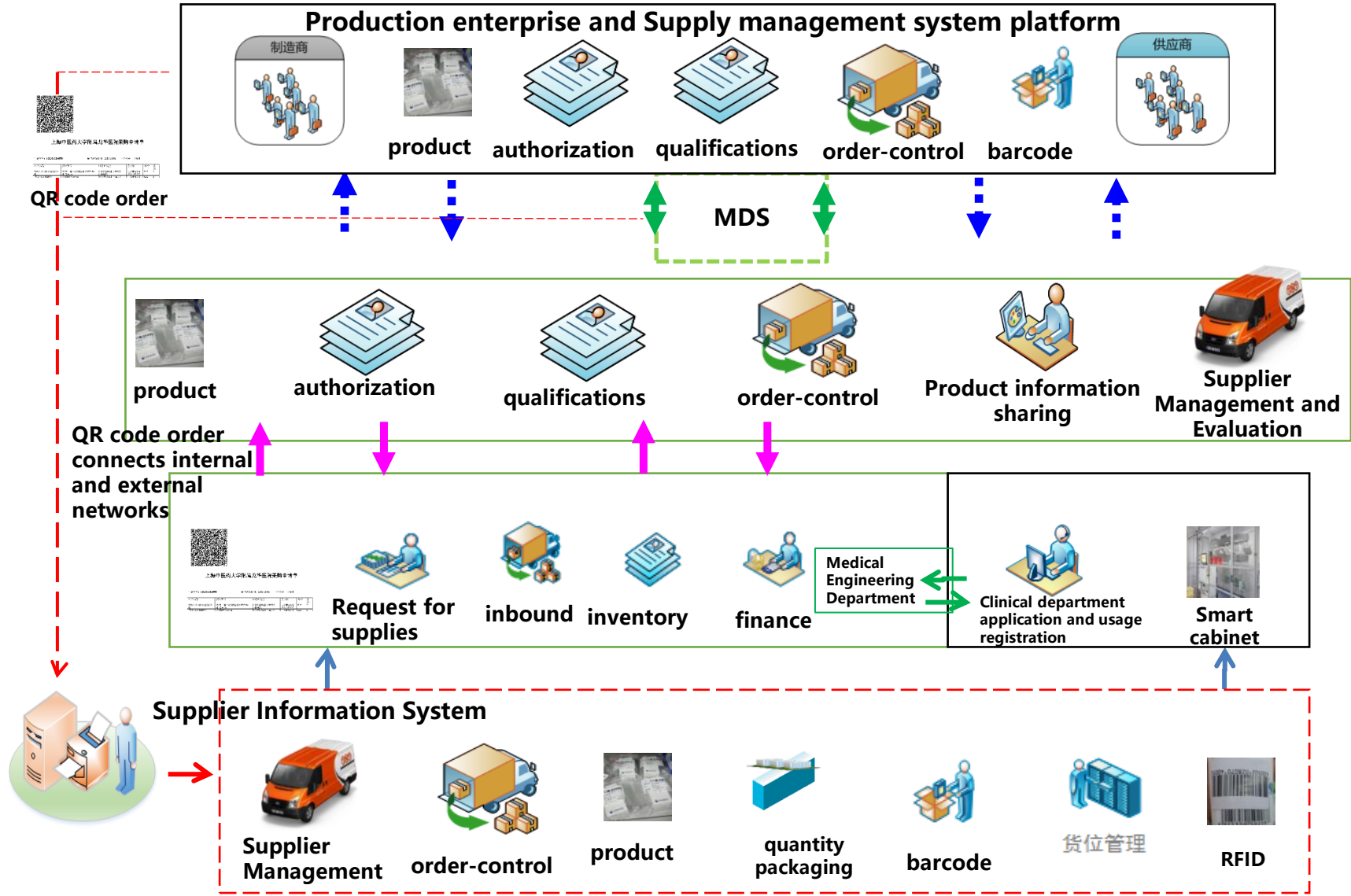
One of the First Demonstration Hospitals for the Implementation of UDI (2022)

/// The Role of UDI in Medical Device Regulation





Intelligent life-cycle management of medical devices based on UDI



Intelligence

Precision

Traceability

Safety

Efficiency

Cost-Cutting



Intelligent life-cycle management of medical devices based on UDI

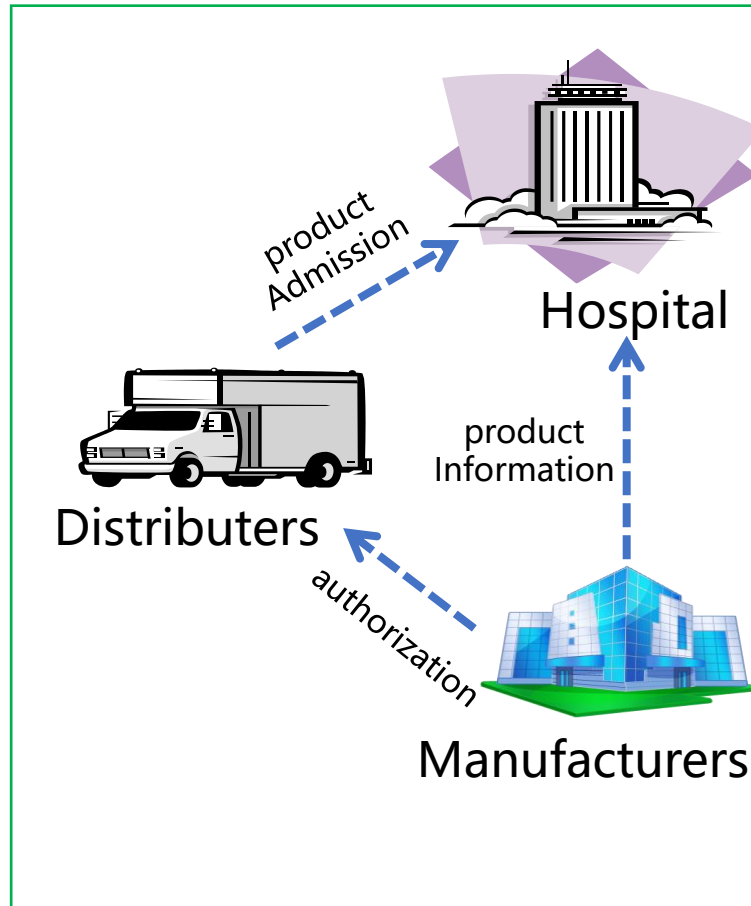


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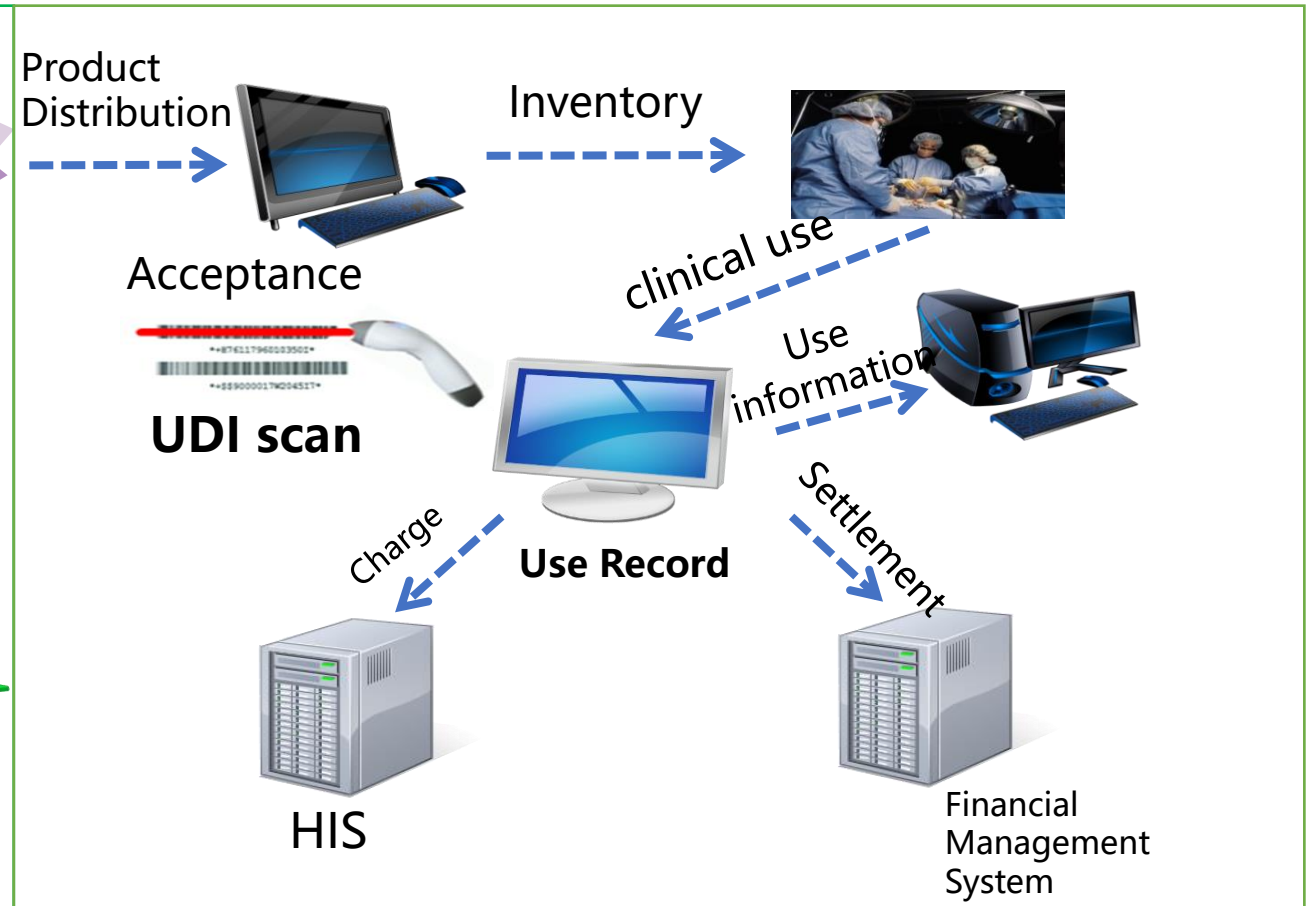


Intelligent life-cycle management of medical devices based on UDI

Internet data service platform (external network)



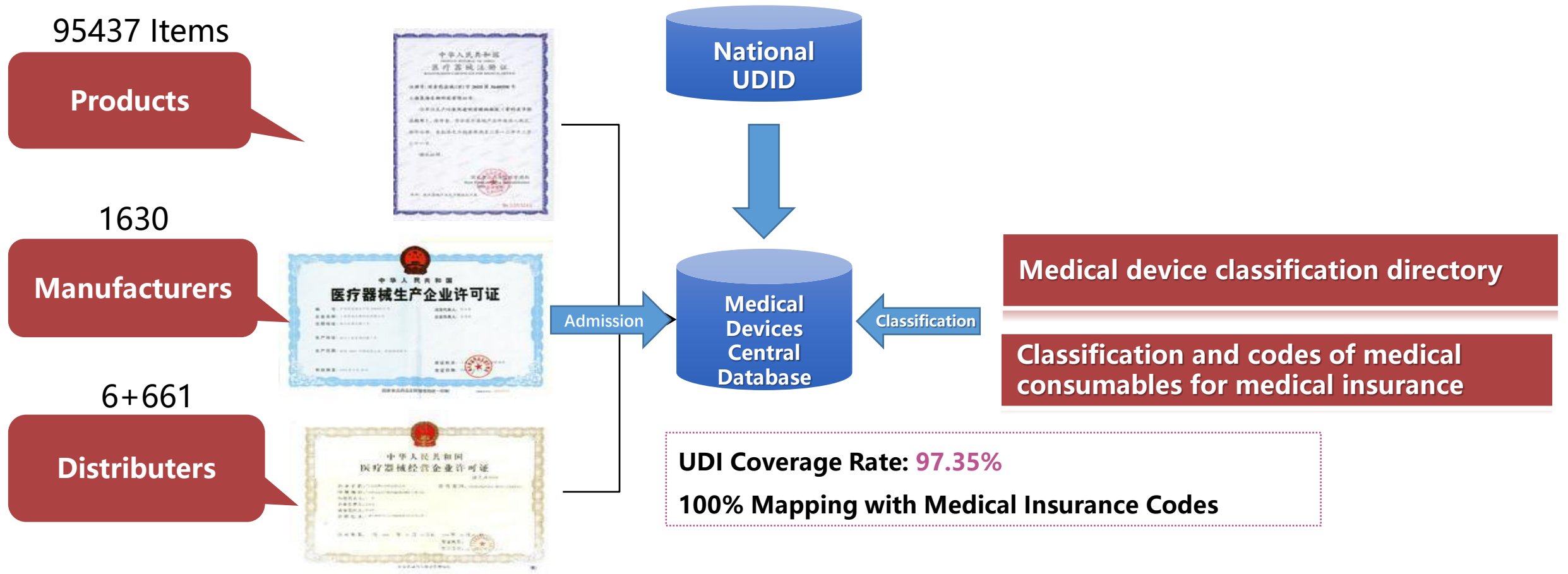
Medical devices management system (internal network)





Application Practice : Product information initialization and database construction based on UDI

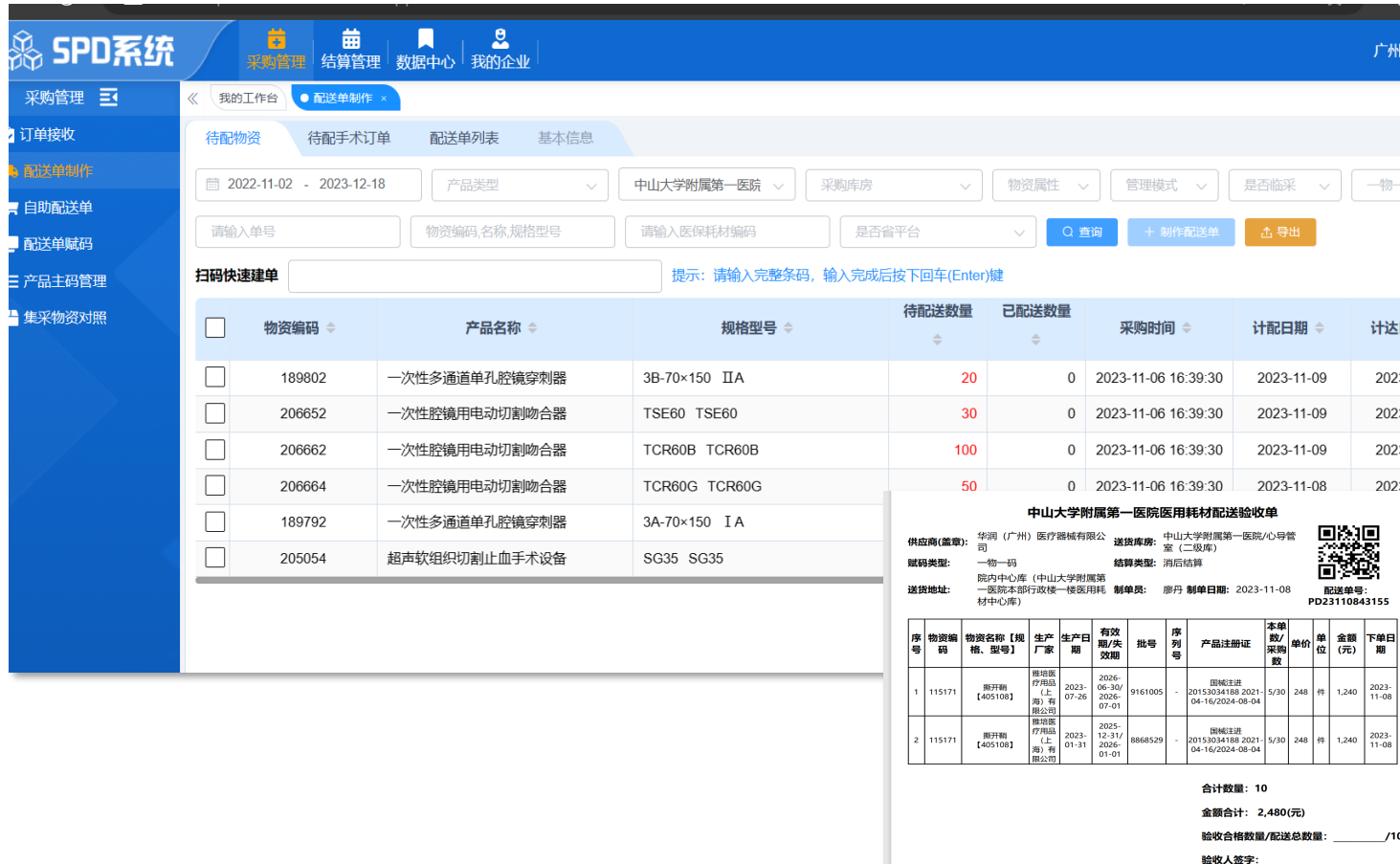
□ Co-building Medical Devices Central Database





Application Practice : Ordering and Delivery information sharing based on UDI

Co-building and Sharing of Supply Chain Information



SPD系统 采购管理 结算管理 数据中心 我的企业 广州

我的工作台 配送单制作

待配物资 待配手术订单 配送单列表 基本信息

2022-11-02 - 2023-12-18 产品类型 中山大学附属第一医院 采购库房 物资属性 管理模式 是否临床 一物一码

请输入单号 物资编码,名称,规格型号 请输入医保耗材编码 是否含平台 查询 + 制作配送单 导出

扫码快速建单 提示: 请输入完整条码, 输入完成后按下回车(Enter)键

物资编码	产品名称	规格型号	待配送数量	已配送数量	采购时间	计配日期	计达日
189802	一次性多通道单孔腹腔镜穿刺器	3B-70×150 IIA	20	0	2023-11-06 16:39:30	2023-11-09	2023-
206652	一次性腔镜用电动切割吻合器	TSE60 TSE60	30	0	2023-11-06 16:39:30	2023-11-09	2023-
206662	一次性腔镜用电动切割吻合器	TCR60B TCR60B	100	0	2023-11-06 16:39:30	2023-11-09	2023-
206664	一次性腔镜用电动切割吻合器	TCR60G TCR60G	50	0	2023-11-06 16:39:30	2023-11-08	2023-
189792	一次性多通道单孔腹腔镜穿刺器	3A-70×150 IA					
205054	超声软组织切割止血手术设备	SG35 SG35					

中山大学附属第一医院医用耗材配送验收单

供应商(盖章): 华润(广州)医疗器械有限公司 送货库房: 中山大学附属第一医院/心导管室(二级库)

物料类型: 一物一码 结算类型: 消后结算

院内中心库(中山大学附属第一医院本部行政楼一楼医用耗材中心库) 制单员: 廖丹 制单日期: 2023-11-08 配送单号: PD23110843155

序号	物资编码	物资名称【规格、型号】	生产厂家	生产日期	有效期/失效期	批号	序列号	产品注册证	本单数量	单价	金额(元)	下单日期
1	115171	康开鞘【405108】	微创医疗用品(上海)有限公司	2023-07-26	2026-06-30/2026-07-01	0161005	-	国械注进20153034188-2021-04-16/2024-08-04	5/30	248	1,240	2023-11-08
2	115171	康开鞘【405108】	微创医疗用品(上海)有限公司	2023-01-31	2026-12-31/2026-01-01	8868529	-	国械注进20153034188-2021-04-16/2024-08-04	5/30	248	1,240	2023-11-08

合计数量: 10
金额合计: 2,480(元)
验收合格数量/配送总数量: _____/10
验收人签字: _____

Hospital:
Send orders through the platform

Distributors:
Prepare products according to orders,
Scan Original UDI Barcode to complete the compliance verification of products

Distributors:
Generate electronic delivery documents with QR Codes

Hospital:
Scan QR Codes to get the Products information and Verification information through the platform

Hospital:
Monitor Delivery Information:
Delivery Time, Quantity, Partial Deliveries, etc.



Application Practice : Acceptance Management based on UDI

□ A built-in validation mechanism to automatically verify the compliance of products



扫码配货

产品名称	房间隔缺损封堵器【FQFDQ-I 34 FQFDQ-I 34】 12000.0000 元/支				
产品注册证	国械注准20173134650				
批号	A/220628(2027-07-15)	序列号	A2255547	有效日期	2027-07-15
生产日期	自 生产日期	灭菌包装	<input type="radio"/> 是 <input checked="" type="radio"/> 否	灭菌日期	自 灭菌日期
配送数量	1	支			

DI信息

PI信息

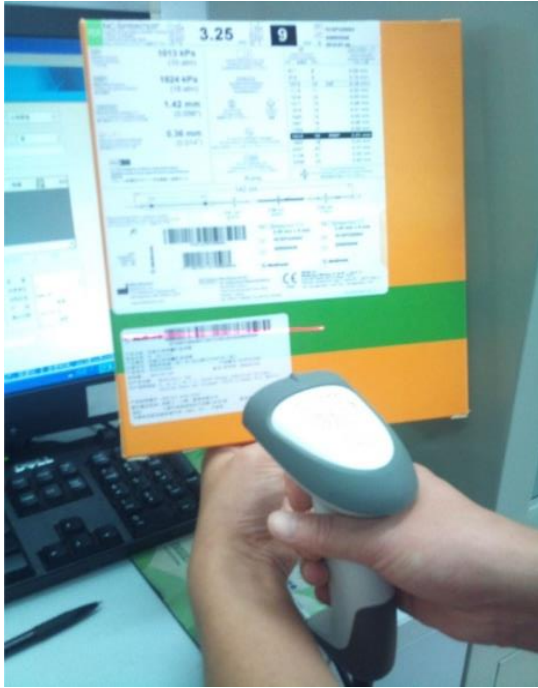
确定 取消



- Through Device Identifier (DI), static product information from the UDI database can be obtained, including, but not limited to, required medical device details such as product name, registration certificate information, device category, specifications, manufacturer, distributor, price, etc.
- Using Production Identifier (PI), dynamic product information such as production batch number, serial number, production date, and expiration date can be parsed and obtained.
- The system incorporates a built-in validation mechanism to automatically verify whether medical devices comply with internal selection criteria, quality conditions, expiration status, etc., generating authentic, complete, and accurate records of incoming inspections.

Application Practice : Application of Lean Six Sigma in Improving the Inspection Process based on UDI

Sharing of Supply Chain Information



Traditional Mode—Scan UDI Barcode to complete the compliance verification of products one by one at hospital
The acceptance time of 200 products is about **45 minutes**

中山大学附属第一医院医用耗材配送验收单

供应商(盖章): 华润(广州)医疗器械有限公司 **送货库房:** 中山大学附属第一医院/心导管室(二级库)
赋码类型: 一物一码 **结算类型:** 消后结算
送货地址: 院内中心库(中山大学附属第一医院本部行政楼一楼医用耗材中心库) **制单员:** 廖丹 **制单日期:** 2023-11-08


配送单号:
PD23110843155

序号	物资编码	物资名称【规格、型号】	生产厂家	生产日期	有效期/失效期	批号	序列号	产品注册证	本单数/采购数	单价	单位	金额(元)	下单日期
1	115171	撕开鞘【405108】	雅培医疗用品(上海)有限公司	2023-07-26	2026-06-30/2026-07-01	9161005	-	国械注进 20153034188 2021-04-16/2024-08-04	5/30	248	件	1,240	2023-11-08
2	115171	撕开鞘【405108】	雅培医疗用品(上海)有限公司	2023-01-31	2025-12-31/2026-01-01	8868529	-	国械注进 20153034188 2021-04-16/2024-08-04	5/30	248	件	1,240	2023-11-08

合计数量: 10
金额合计: 2,480(元)
验收合格数量/配送总数量: _____/10
验收人签字: _____

Lean Optimization—Distributors: Scan UDI Barcode to complete the compliance verification of Products when they Prepare products, Hospital: Scan QR Codes to get the Products information and Verification information through the platform.
The acceptance time of 200 products is less than **10 minutes**

Application Practice : Utilization Management (Core of Quality Control and Management)

- Scan Original UDI Barcode to Verify the Validity of Products again, record product information and create electronic use records (OR)



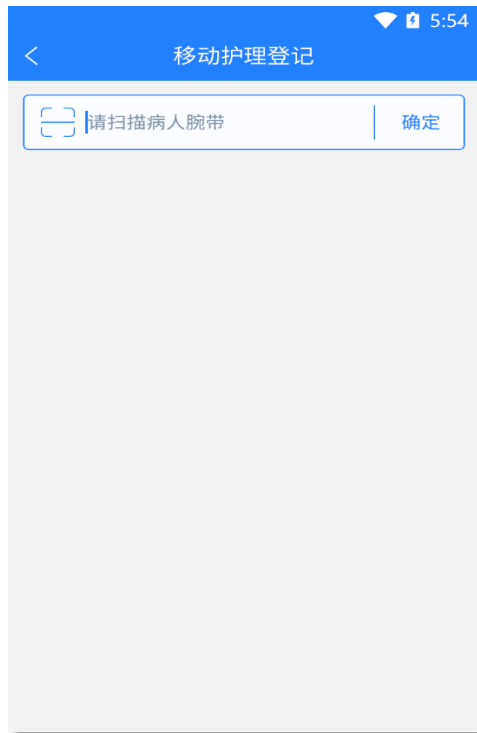
通过UDI识别该耗材的DI码和PI码以及该耗材的管理属性等



Application Practice : Utilization Management (Core of Quality Control and Management)

Trace Clinical use behavior

Based on the UDI code, through the SPD system and mobile nursing linkage (Inpatient Wards)



Scan patient
wristband

Scanning UDI
Barcode

Clinical use records of
medical consumables

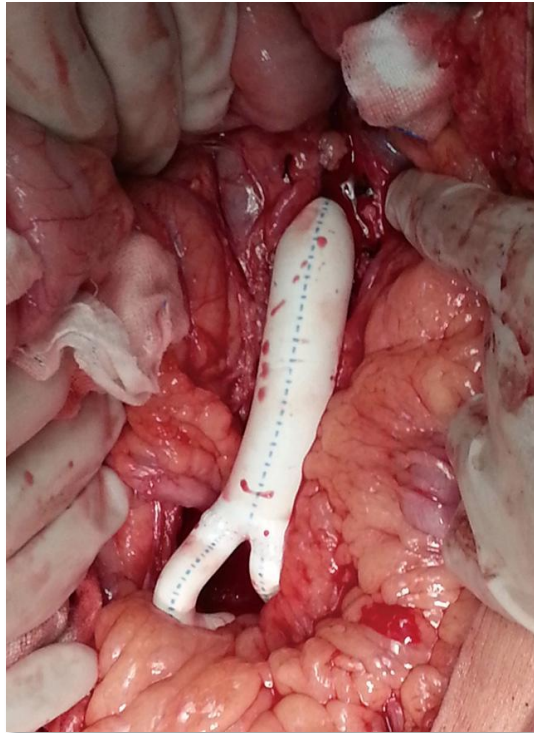
Mobile Care Billing



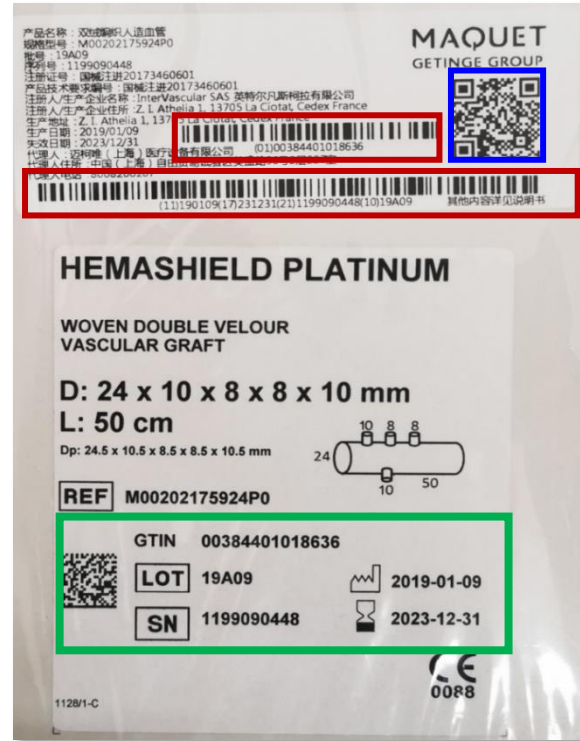
Application Practice : Utilization Management (Medical insurance and Settlement)



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medical devices



UDI

国家医保信息业务编码标准数据库动态维护

医用耗材分类目录 医用耗材信息

一级分类: 二级分类: 三级分类: 耗材名称: 规格/特征: 品牌:

医用耗材分类代码	三级分类代码	一级 (学名、品名)	二级 (用途、品目)	三级 (部位、功能、品种)	医保通用名	转码	材料名称	规格	品牌 (特征、商标)
S1 C02050100100001	C020501	血管介入治疗类材料	神经介入治疗材料	颅内支架	001 支架	00	不区分	001	支架/无头端
S2 C02050100100005	C020501	血管介入治疗类材料	神经介入治疗材料	颅内支架	001 支架	00	不区分	005	普通支架/动脉瘤辅助/有头端
S3 C02050100100006	C020501	血管介入治疗类材料	神经介入治疗材料	颅内支架	001 支架	00	不区分	006	普通支架/动脉瘤辅助/无头端
S4 C02050100100007	C020501	血管介入治疗类材料	神经介入治疗材料	颅内支架	001 支架	00	不区分	007	普通支架/颈动脉扩张/有头端
S5 C02050100100008	C020501	血管介入治疗类材料	神经介入治疗材料	颅内支架	001 支架	00	不区分	008	普通支架/颈动脉扩张/无头端
S6 C02050100100009	C020501	血管介入治疗类材料	神经介入治疗材料	颅内支架	001 支架	00	不区分	009	密网支架/动脉瘤辅助/有头端
S7 C02050100100010	C020501	血管介入治疗类材料	神经介入治疗材料	颅内支架	001 支架	00	不区分	010	密网支架/动脉瘤辅助/无头端
S8 C02050100100011	C020501	血管介入治疗类材料	神经介入治疗材料	颅内支架	001 支架	00	不区分	011	密网支架/颈动脉扩张/有头端
S9 C02050100100012	C020501	血管介入治疗类材料	神经介入治疗材料	颅内支架	001 支架	00	不区分	012	密网支架/颈动脉扩张/无头端

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Medical insurance code

Establish the relationship between medical devices and information (records) with AIDC model

Two codes mapping

Procurement-Use-Settlement Consistency Association



Application Practice : Quality and Clinical use monitoring



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Quality monitoring:
Adverse events and Recalls

Quickly locate the safe use and inventory situation, including the use of patients, the number of use cases, inventory quantities, manufacturers, etc.

Authentic, accurate, comprehensive, precise and loop-locked use data of medical devices to help monitor and analyze the consumption of medical devices for better Management and Cost control

Clinical Use monitoring:
Clinical use management

可以通过产品UDI或者患者等信息轻松追溯

序号	医疗器械编码	产品名称	规格型号	是否特殊器械材料	单价/元	消耗金额	开单科室	住院号	病人姓名	手术名称	手术日期	库号
1	C032507089200109098	脊柱后路内固定系统	179702000 179702000	否	10	10	综合三区	0031066851 j6400	万博森	腰椎间盘切除 伴椎管减压术	2023-11-01	99548R
2	C032502089010080698	脊柱前路内固定系统	186789150 186789150	否	45	45	综合三区	0031066851 j6400	万博森	腰椎间盘切除 伴椎管减压术	2023-11-01	99548R
3	C1408031850001405039	可吸收性外科缝线	4-0 VLA2000G	否	100	100	综合三区	0031066851 j6400	万博森	腰椎间盘切除 伴椎管减压术	2023-11-01	99548R
4	C150107212000200908	可吸收止血海绵颗粒	M50010 M50010	否	2830	2830	综合三区	0031066851 j6400	万博森	腰椎间盘切除 伴椎管减压术	2023-11-01	99548R
5	C0347021000000100502	同种骨植入材料	1g 专用骨件 (冻干表面)	否	7400	7400	综合三区	0031066851 j6400	万博森	腰椎间盘切除 伴椎管减压术	2023-11-01	99548R
6	C0325070890200109098	脊柱后路内固定系统	179702000 179702000	否	10	10	综合三区	0031066851 j6400	万博森	腰椎间盘切除 伴椎管减压术	2023-11-01	99548R
7	C032502089010080698	脊柱前路内固定系统组件	186789150 186789150	否	45	45	综合三区	0031066851 j6400	万博森	腰椎间盘切除 伴椎管减压术	2023-11-01	99548R
8	C0325070890200109098	脊柱后路内固定系统	179702000 179702000	否	10	10	综合三区	0031066851 j6400	万博森	腰椎间盘切除 伴椎管减压术	2023-11-01	99548R
9	C0325070890200109098	脊柱后路内固定系统	179702000 179702000	否	10	10	综合三区	0031066851 j6400	万博森	腰椎间盘切除 伴椎管减压术	2023-11-01	99548R
10	C032500890100490908	脊柱后路内固定系统	179712650 179712650	否	170	170	综合三区	0031066851 j6400	万博森	腰椎间盘切除 伴椎管减压术	2023-11-01	99548R
11	C03470411000000050986	骨修复材料	1.2mg mBMP-2 1.2mg...	否	4108	4108	综合三区	0031066851 j6400	万博森	腰椎间盘切除 伴椎管减压术	2023-11-01	99548R

可以通过UDI或者其他产品信息轻松定位科室剩余物资

序号	物资编码	名称	规格型号	品牌(厂家)	规格	数量	单位	操作
1	143032	手术室一区5F 高级库号 (二级库)	髋膝成形环	【北京信仁医疗科技股份有限公司】	25 C形环	2	盒	Q
2	143033	手术室一区5F 高级库号 (二级库)	髋膝成形环	【北京信仁医疗科技股份有限公司】	27 C形环	4	盒	Q
3	142995	手术室一区5F 高级库号 (二级库)	髋膝成形环	【北京信仁医疗科技股份有限公司】	29 C形环	2	盒	Q
4	143034	手术室一区5F 高级库号 (二级库)	髋膝成形环	【北京信仁医疗科技股份有限公司】	31 C形环	2	盒	Q
5	197595	手术室一区5F 高级库号 (二级库)	髋膝成形环 Annu...	【爱博华(上海)医疗用品有限公司】	6200T28 6200T28	5	个	Q
6	197596	手术室一区5F 高级库号 (二级库)	髋膝成形环 Annu...	【爱博华(上海)医疗用品有限公司】	6200T30 6200T30	3	个	Q
7	197597	手术室一区5F 高级库号 (二级库)	髋膝成形环 Annu...	【爱博华(上海)医疗用品有限公司】	6200T32 6200T32	3	个	Q



Application Practice : Applications of intelligent facilities and equipment based on UDI and RFID



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□ Intelligent inventory management of high-value medical devices



Smart warehouse



**operating room
area 1**

Smart cabinets and Smart walls



Application Practice : Applications of intelligent facilities and equipment based on UDI and RFID

□ Intelligent inventory management of consumables



Customized smart cabinet



Suture and hemostatic material management

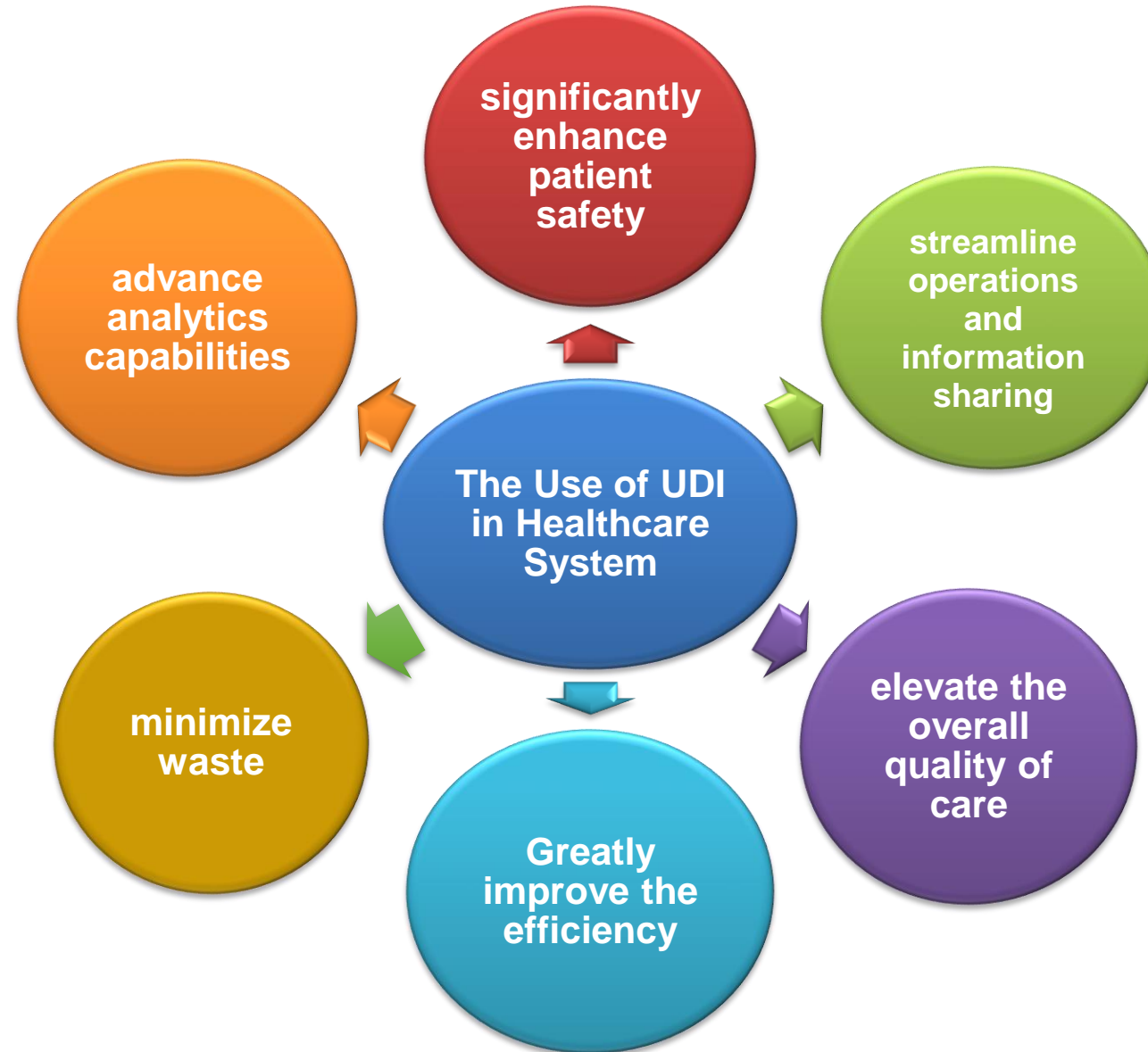


RFID refrigerated smart cabinet

Through customized intelligent equipment, refined management of consumables such as sutures, guidewire catheters, and hemostatic material can be achieved



The benefits from the use of UDI





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Thank you

Donglan Yu

The First Affiliated Hospital, Sun Yat-sen University

