

医用塑料产品的注塑方案

Medical Applications by Injection Molding

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多组份注塑 - Multicomponent

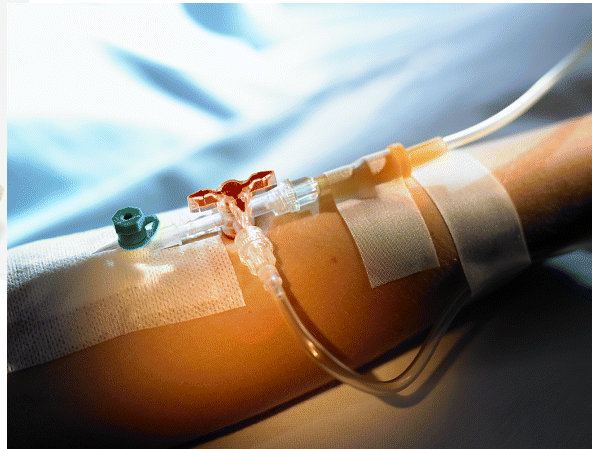


输液阀 - 多组份，模内装配

Valve – Multicomponent and In-mold Assembly



模腔数/Cav	4 + 4
件重/Part Weight	2.3 [g]
材料/Material	PC
循环周期/Cycle Time	42s



自动化 - Automation

血液分配管— 自动化镶嵌注塑

Blood Distributor – Automation Insert Molding

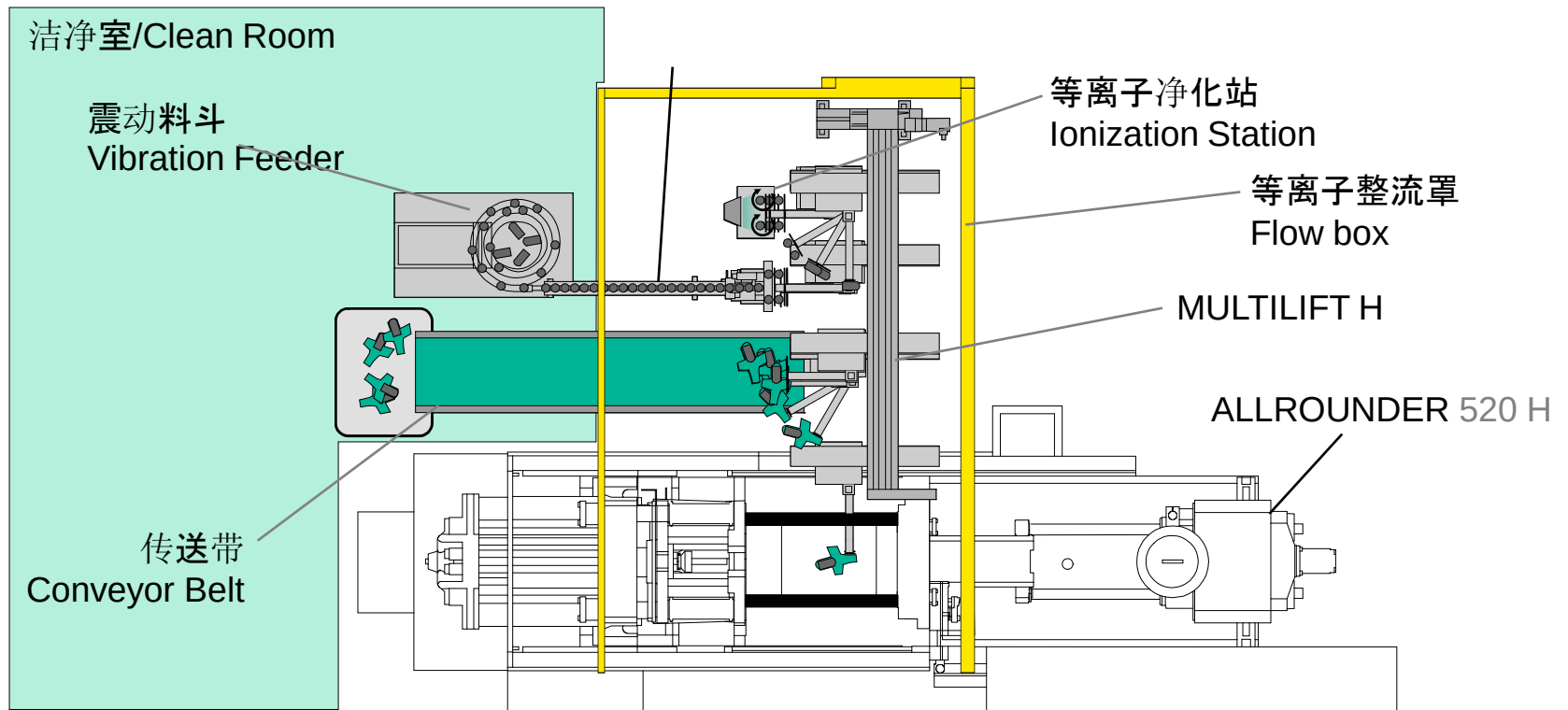


模腔数/Cav	2
件重/Part Weight	6 g
材料/Material	PC
循环周期/Cycle Time	16s

自动化 - Automation

血液分配管— 自动化镶嵌注塑/洁净室方案2

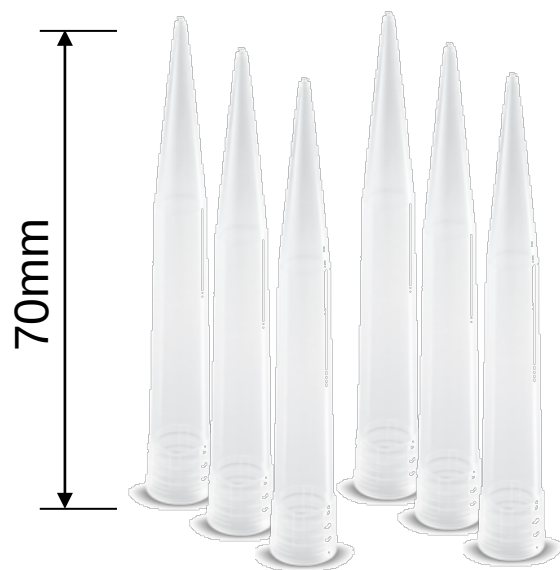
Blood Distributor – Automation/Insert-molding/Clean room Solution2



自动化 - Automation

吸液管- 快速成型/集成检测（100%）/洁净室方案2

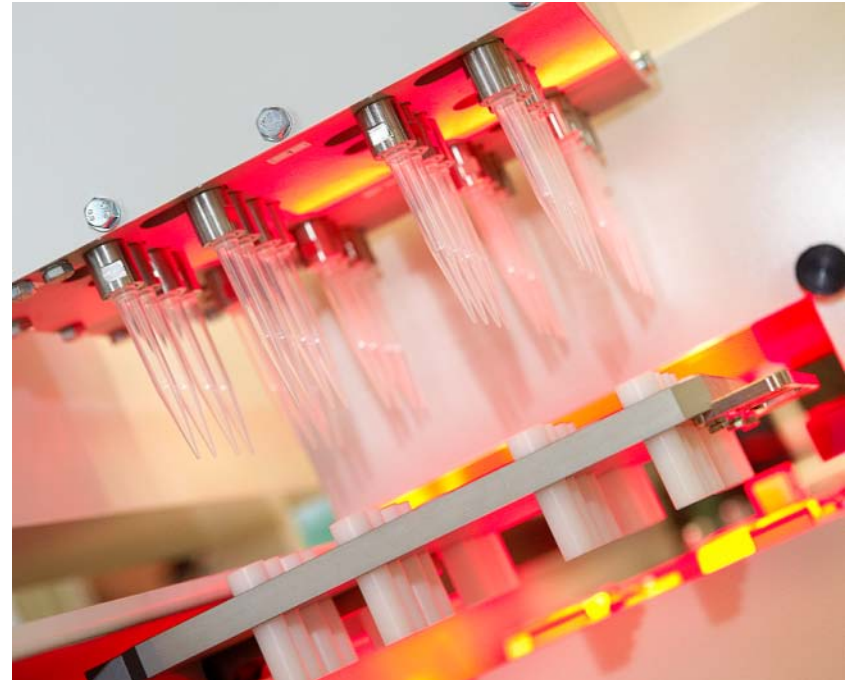
Pipette – fast cycle/100% integrated QA / Clean Room Sol.2



模腔数/Cav	32
件重/Parts Weight	0.7 [g]
材料/Material	PP
循环周期/Cycle Time	5.9s
机器人进出/Robot Time	0.4s

自动化 - Automation

吸液管- 快速成型/集成检测（100%）/洁净室方案2
Pipette – fast cycle/100% integrated QA / Clean Room Sol.2



高精密度可回溯注塑 High Precision & Traceability



人工呼吸器/Artificial Lunge

- 直接与血液接触/direct contact with blood
- 原材料必须是经认证的医用原料/Certificated material for med. App.
- 高度无尘无菌/High clean room classification ISO 5/6
- 耐高温消毒，耐磨损/High temp. & high wear resistant
- 机械强度/Robust
- 100% 质量检验/QA
- 生产过程存档/traceability of all parts



液态硅胶注塑 – LSR

人造眼晶体 - 液态硅橡胶注塑/微型注塑
Artificial Crystalline lens – LSR/Micro Injection

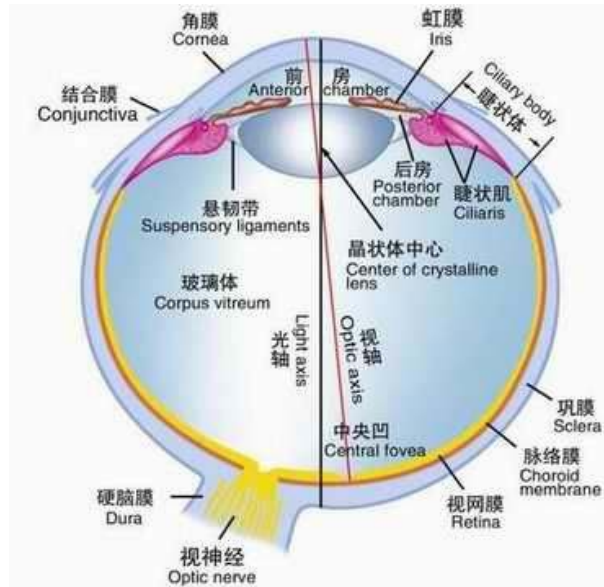


图 眼球的水平切面



液态硅胶注塑 - LSR

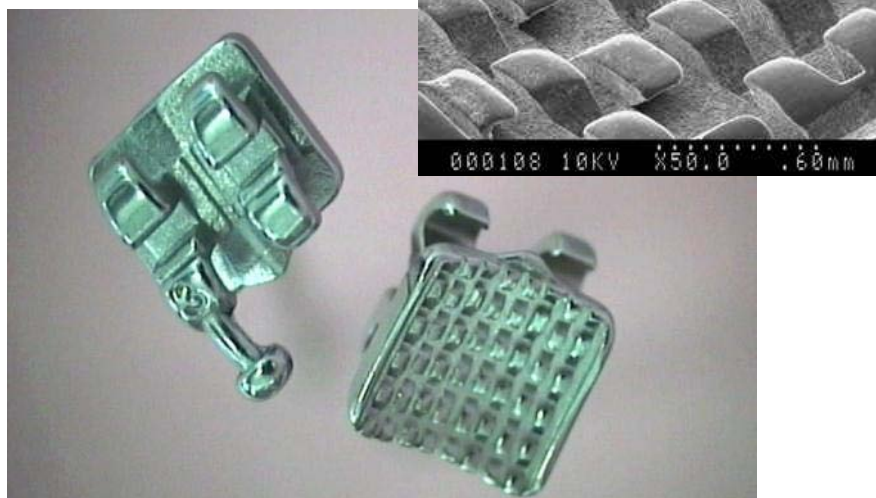
呼吸面罩及导尿管- 液态硅橡胶注塑/镶嵌注塑
Mask & Catheter – LSR/Insert Molding



粉末注塑 - PIM

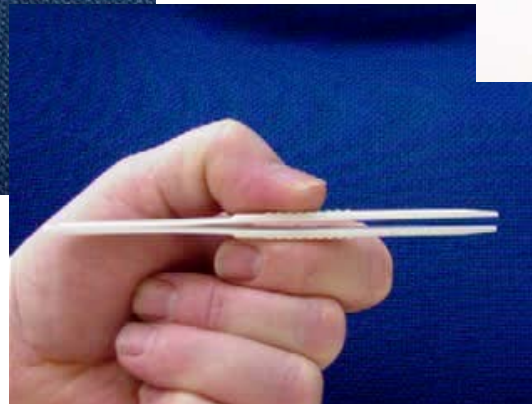
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牙箍（不锈钢17-4）及牙钉（陶瓷ZTA）
Dental Bracket (17-4 PH) & Tooth Implant (ZTA)



粉末注塑 - PIM

手术刀，医用镊子（陶瓷 ZrO_2 ）及医用探头（陶瓷 Si_3N_4 ）
Scalpel, Tweezers (ZrO_2) & Probe Head (Si_3N_4)



粉末注塑 - PIM

取样钳（陶瓷ZTA20，不锈钢17-4，钛合金）
Probe Heads (ZTA20, 17-4PH, Ti)

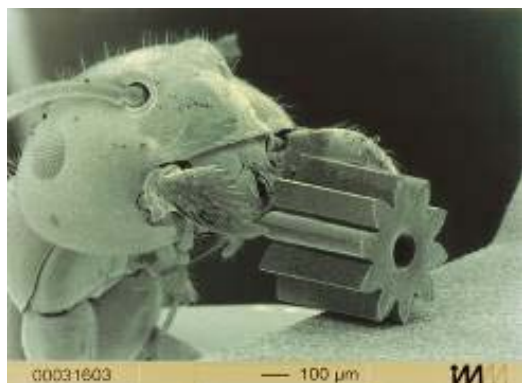


微型注塑 – Micro Injection

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微创血栓清除针

Microsurgery Thrombus Cleaner



输液阀 – Transfusion Valve

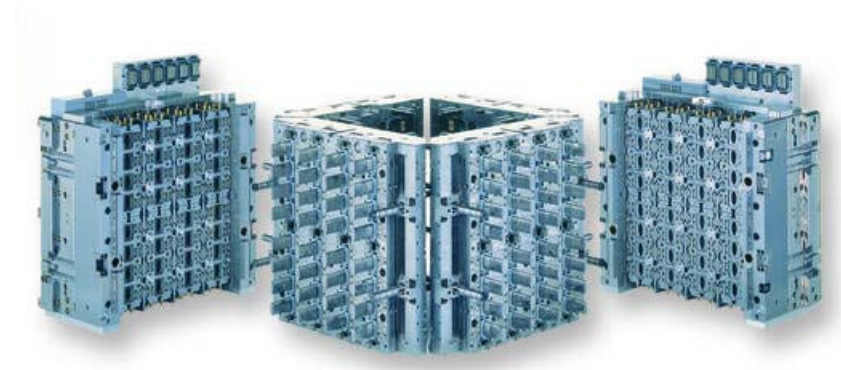


模腔数/Cav	16
件重/Part Weight	1 [g]
材料/Material	PC
循环周期/Cycle Time	12s

快速成型 – Fast Cycle

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真空采血管 – 快速成型 Vacuum Vessel – Fast Cycle



	标准 Conventional	Cube Mold
模腔数/Cav	96	96
件重/Part Weight	3.25	3.25
材料/Material	PET- A	PET- A
循环周期/Cycle time	8-10s	5-6s

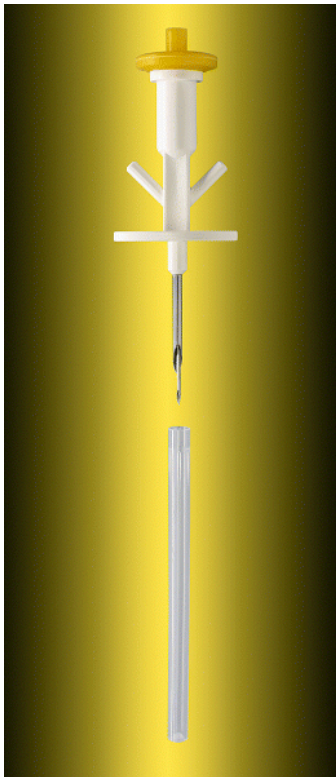
真空采血管 – 快速成型 Vacuum Vessel – Fast Cycle

类别	添加剂 代号	管盖颜色	添加剂名称	使用范围	是否为 无菌
无添加剂	A	红色	无	用于生化、免疫、血清等检验血液 样本的采集和贮存	否
促凝管	B	红色	促凝剂	用于生化、免疫、血清等检验血液 样本的采集和贮存	否
分离胶管	C	金黄色	促凝剂+分离胶	用于生化、免疫、血清等检验血液 样本的采集和贮存	否
血常规管	D	淡紫色	K2EDTA	用于血液学血常规、全血检测	否
血凝管	E	浅蓝色	3.2%枸橼酸钠与 血样 比例为1:9	用于凝血机制（PT, APTT, 凝血因子） 检测	是
血沉管	F	黑色	3.8%枸橼酸钠与 血样 比例为1:4	用于血细胞沉降率检测	是
肝素管	G	绿色	肝素钠、肝素锂	用于快速血浆生化、血流变检测	否
血糖管	H	灰色	氟化钠+EDTA	用于血糖值的检测，能较长时间保持 血液样本的原始性状	否

快速成型 – Fast Cycle

留置针 – Retention Needle

模腔数/Cav	64
材料/Material	PP
循环周期/Cycle Time	6.9s



适合于医疗产品生产的洁净室

Clean Room for Medical Parts Production

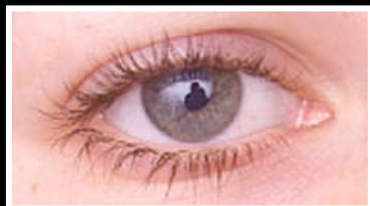
EN ISO 14644*	Central regulations for clean room classes 洁净室等级核心标准
EN ISO 13485	Quality management for medical products 医疗产品质量管理标准
VDI 2083	Clean room technology 洁净室技术标准
EU Directive 2001/83/EC	Code for human pharmaceuticals 人体医药标准
GMP	Goods Manufacturing Practices 医疗制品生产质量规则
FDA	Food and Drug Administration 美国联邦食品和药物管理规则
Individual specifications/ factory standards	个体企业生产规定

* Replaces US Federal Standard 209E and comparable to its classification/ 取代美国联邦标准209E及等同标准

适合于医疗产品生产的洁净室

Clean Room for Medical Parts Production

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可见/Visible
大于/bigger than $10\text{ }\mu\text{m}$



目标:保护医疗制品不受空气传播污染, 包括: 粉尘, 花粉, 细菌, 病毒, 空气中的悬浮物

Purpose: protect the medical products from pollution of e.g. dust,bacteria,virus



不可见/invisible
小于/smaller than $10\text{ }\mu\text{m}$

$5\text{ }\mu\text{m}$

$0.1\text{ }\mu\text{m}$

在洁净室内需要控制的颗粒尺寸

The particles to be controlled in the clean room

适合于医疗产品生产的洁净室

Clean Room for Medical Parts Production



每立方米空气中颗粒尺寸及数量决定了洁净室等级

Particle qty & size/m³ - the class of the clean room

按照EN ISO 14644 / previous US Fed. Std.	每立方米空气中颗粒含量/Particles per m ³					
	0.1 µm	0.2 µm	0.3 µm	0.5 µm	1 µm	5 µm
ISO 1	10	2	-	-	-	-
ISO 2 / 0	100	24	10	4	-	-
ISO 3 / 1	1,000	237	102	35	8	-
ISO 4 / 10	10,000	2,370	1,020	352	83	-
ISO 5 / 100	100,000	23,700	10,200	3,520	832	29
ISO 6 / 1,000	1,000,000	237,000	102,000	35,200	8,320	293
ISO 7 / 10,000	-	-	-	352,000	83,200	2,930
ISO 8 / 100,000	-	-	-	3,520,000	832,000	29,300
ISO 9	-	-	-	35,200,000	8,320,000	293,000

最高医疗制品洁净标准
Highest class ISO 5

典型注塑生产的医疗制品（如注射器，输液盖等）的洁净等级
Typical for injection molding

适合于医疗产品生产的洁净室

Clean Room for Medical Parts Production

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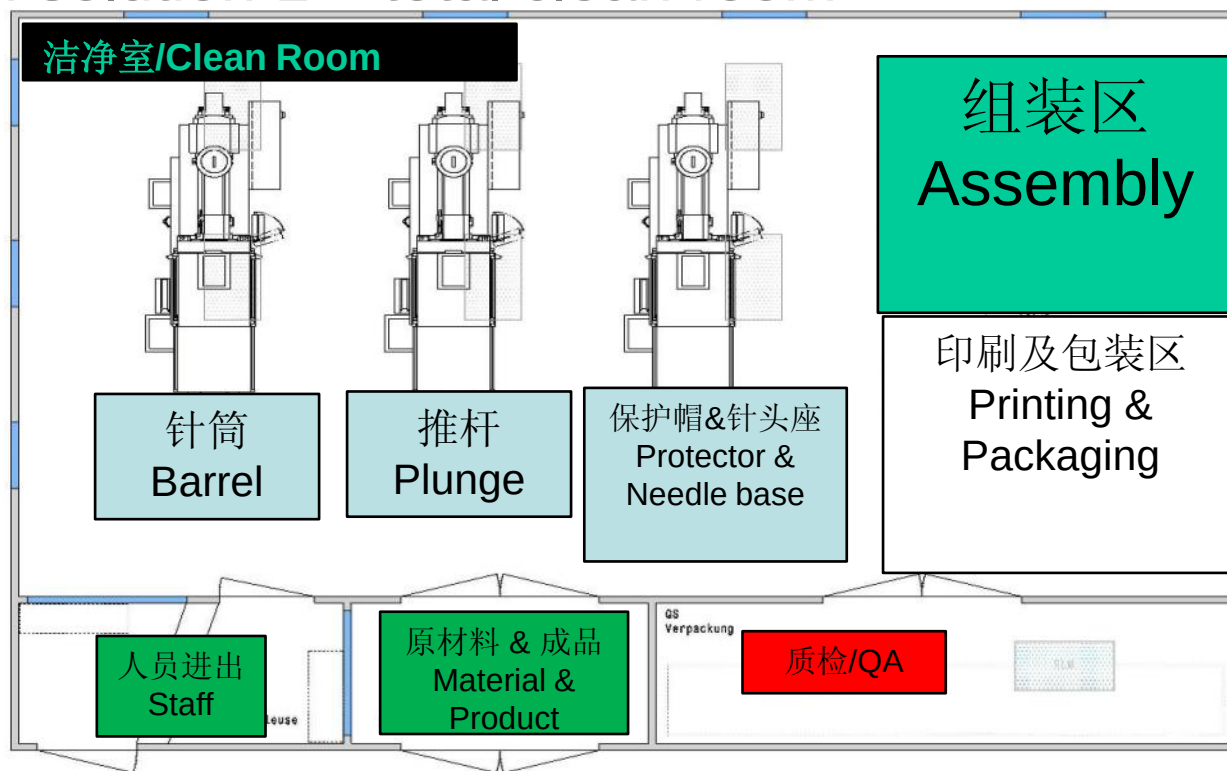
污染源/Pollution Source			后果/Result	发生频率/Frequency	解决办法/Solution
人员/Human			最大的污染源，带来粉尘，病菌及涡流传播污染 The largest pollution, brings dust, bacteria and turbulence	一直发生/always	尽量减少人员/to reduce human activity in clean room
机器/Machine	全电动机 Full. El.	曲臂/Toggle	润滑油完全暴露在空气中，油汽的蒸发 Exposures of lubrication oil, transpiration	一直发生/always	不可避免/inevitable
		伺服马达的冷却 Cooling servo motor	风扇产生的涡流产生局部粉尘集中及传播粉尘等 Fan causes turbulence and particles concentration	一直发生/always	可改为水冷 water cooling
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Clean Room for Medical Parts Production

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方案1 全洁净室

Clean room solution 1 – total clean room



适合于医疗产品生产的洁净室

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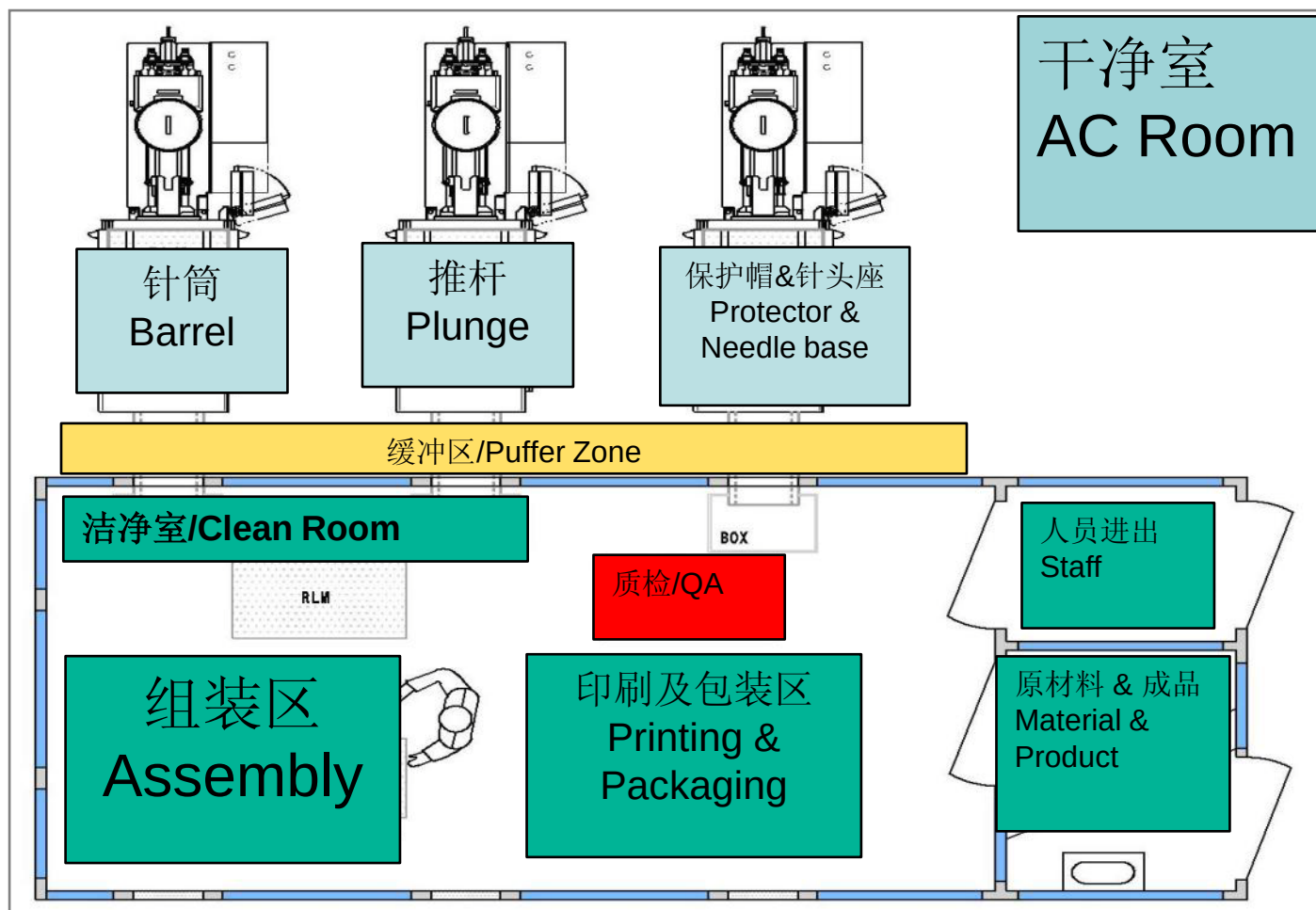
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适合于医疗产品生产的洁净室
Clean Room for Medical Parts Production

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方案2 接驳洁净室 – Solution 2 Docking Solution



适合于医疗产品生产的洁净室

Clean Room for Medical Parts Production

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适合于医疗产品生产的洁净室

Clean Room for Medical Parts Production



Clean room	8 x 100T IMM inside	8 x 100T IMM outside docked
Area m ²	330	90
Height	4,5	2,8
Air Rate, total m ³ /h	62,000	11,000
cooling power (min.) kW	260	50
Heating power	120	40

最大受益：极度降低洁净室建造，运行成本及污染风险

案例/Case Study

一次性注射器/One-way syringe

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模具要求/Mold Requirements

材料要使用防腐蚀钢材
Corrosion resistant steel

表面涂层避免使用润滑剂
Coating instead of lubrication

易于清洁,易于装配
Easy to dis-/assembly & clean

要使用无泄漏冷水机,冷水机内要使用纯净水
Distilled water as cooling water, leakage free chiller



芯子同心度/Coaxiality

芯子冷却技术/Core cooling

模具设计寿命 5-10年
Mold's life time 5-10 years

全热流道系统,多流道平衡
Full hot runner and multi-cav. balance

如需求超大所有制品可考虑实现叠模

Stack mold possible due to huge qty

效率 - Efficiency



产品/Products	腔数 Cav	循环周期 Cycle	机器 Machine	备注 Comments
针筒/Barrel 5ml/10ml	24-48	7 - 8	100T – 200T	5ml标准壁厚0.8/0.9mm，趋势：0.55mm 5ml from 0.8/0.9mm -> 0.55mm Stack mold possible
针筒/Barrel 1ml/3ml/20ml	24-48	8.5-9.5	100T – 200T	可采用叠模提高产能 Stack mold possible
推杆/Plunge	24-48	7-8	150-200T	可采用叠模提高产能（88+88） Stack mold possible
保护套/Protector	64	8-9	100T	可采用叠模提高产能（144+144） Stack mold possible
针头座/Needle Base	96	8-9	150T	可采用叠模提高产能（144+144） Stack mold possible

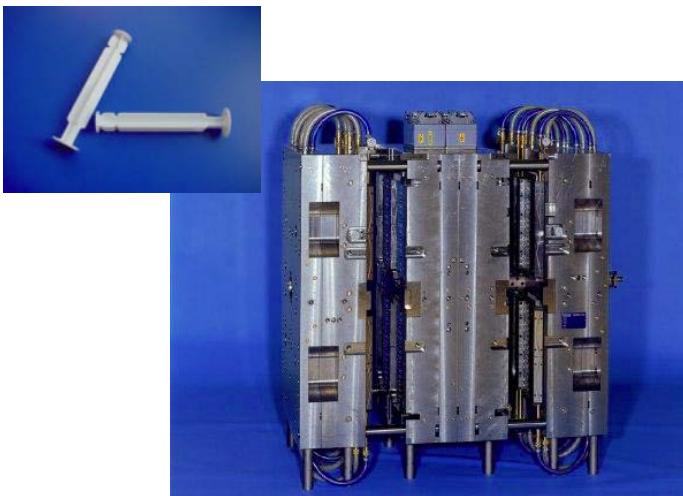
模具供应商 – Mold Makers



	模具商 Mold Maker	优势 Advantages	弱势 disadvantages
国外 Abroad	Forstaq, Tanner, Schoettli	高产能，高可靠性，叠模技术，自己的热流道系统,100%流道平衡，几十年产业经验 High efficiency, high reliability, stack mold techn., decades exp.	价高，对材料要求高，除Schoettli外在中国没有售后 High price, high requirement on material's MFR, except. of Schoettli, no service in china
国内 Domestics	2家合作厂 2 partners	价格低，部分产能接近国外标准，本地售后服务，国产原材料（如赛科的PP） Low price, some close to European eff., local service, local material (e.g. Secco PP, MFR 12)	几年的产业经验，可靠性有待认证，无自产热流道，无法做到100%流道平衡，叠模技术有待开发 Several years exp., reliability to be proven, no own hot runner, 100% gate balance seldom, stack mold under development

叠模 – Stack Mold

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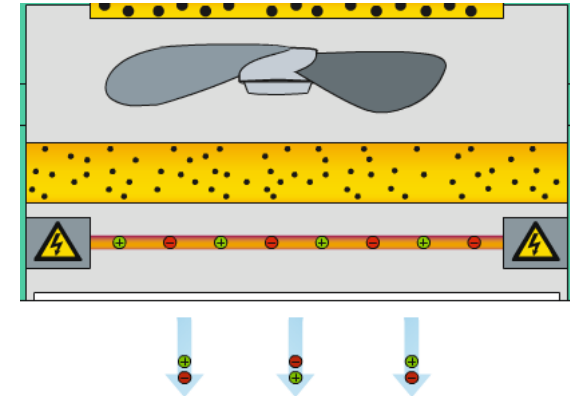


80+80 2ml 推杆, 7.5s



64+64 2ml 针筒, 8.9s

注塑机的洁净室适配 Injection Molding Machine for Clean Room Production



注塑机的洁净室适配 IMM for Clean Room Production

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注塑机的洁净室适配

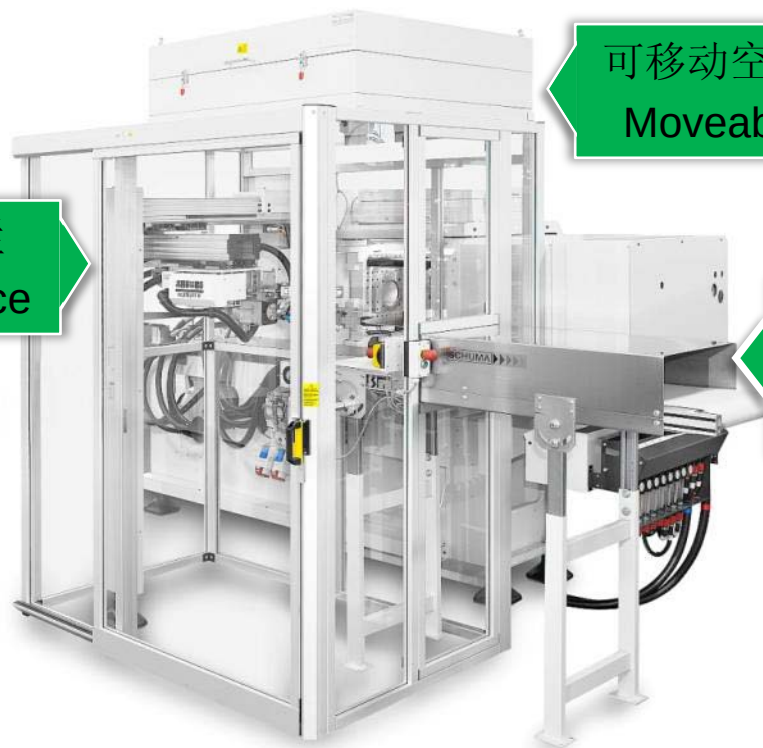
IMM for Clean Room Production

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注塑机的洁净室适配 IMM for Clean Room Production

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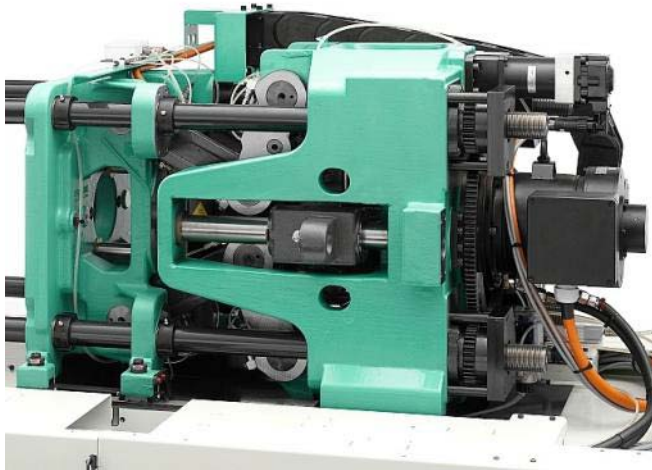
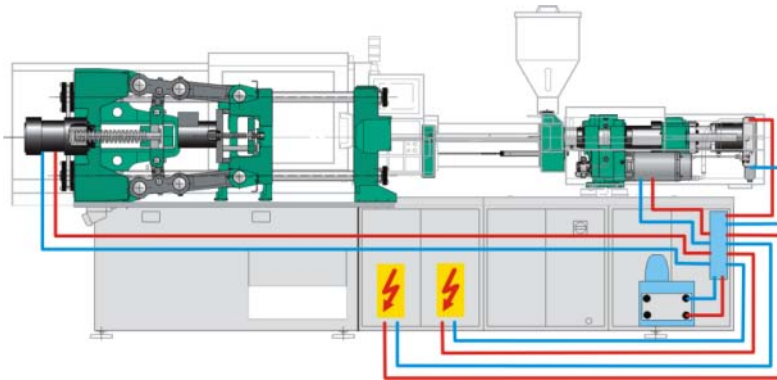
封闭式机器手PC透明围栏
Close PC transparent fence

可移动空气过滤整流罩
Moveable Flow Box

封闭式联接洁净室传送带
Close convey belt to
clean room

用于快速成型的高速机 – ARBURG H IMM for Fast Cycle – ARBURG H

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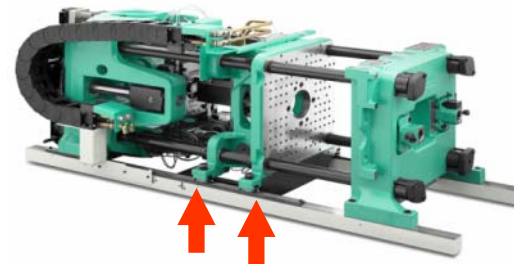
合模系统/Clamping Unit:

-水冷的伺服马达 – 洁净室，高速降温，精度
Water cooled Servo Motor – clean room, high cooling eff. at high speed movement, long term high precision

-伺服马达调模厚 – 实时监控锁模力，保护模具及机器
Mold height adjustment by servo motor – real time clamping force monitoring and regulation, protection of mold and machine

-箱式12点支撑合模机构 – 保护模具，保证高速合模时导向
Box structure – mold protection, high precise guidance at high speed movement

-动能回收 – 节能
Kinetic energy to electricity – energy saving

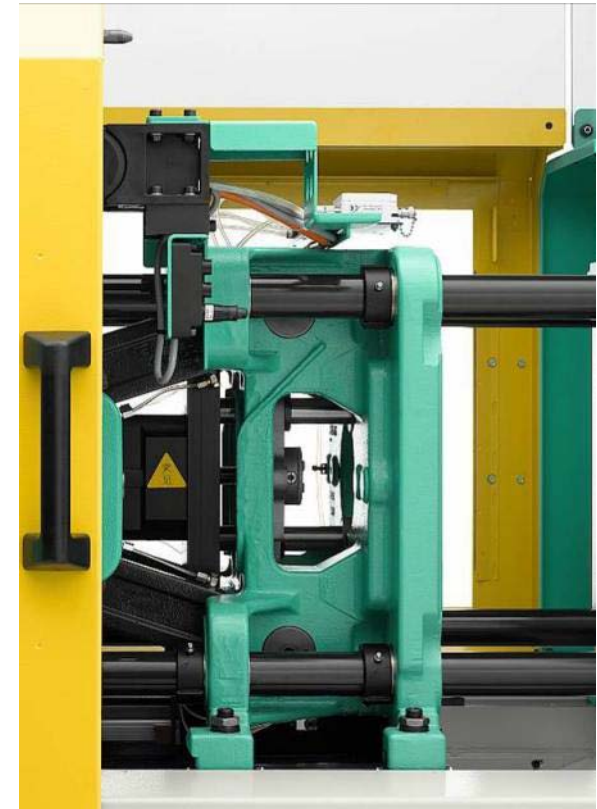


用于快速成型的高速机 – ARBURG H IMM for Fast Cycle – ARBURG H



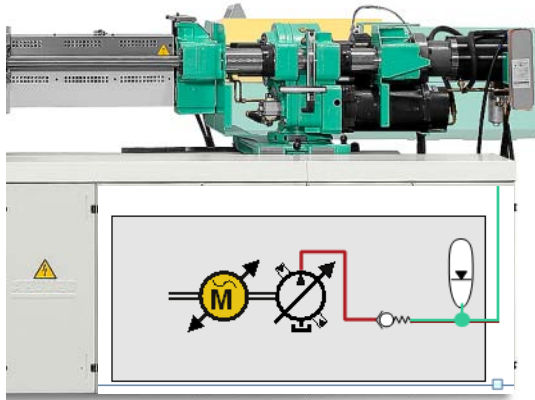
顶针/Ejector

- 提高效率，避免产品污染 – 开模与顶针同步
- Shorten cycle, avoid contamination – synchronized ejection
- 模具要求 - 最大顶针力和行程与液压机相同
- Mold requirement – strong full el. Ejector same as hydraulic
- 顶针配快速连接器，易于装模
- Quick coupling, easy to mount



用于快速成型的高速机 – ARBURG H IMM for Fast Cycle – ARBURG H

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注塑系统/Injection Unit:

- 采用双拉杆对称施加喷嘴接触力 - 无漏料
- Symmetric tie bars for nozzle contact force – no material leakage
- 料筒热绝缘 – 洁净室要求
- Thermo isolation – clean room requirement
- 配分离式螺杆的大功率射台 – 塑化功率
- High power injection unit with barrel screw as option – material throughput
- 氮气蓄能器技术 – 高加速度注射 – 薄壁/同心度
- Full accumulator – high acceleration – thin wall/coaxiality

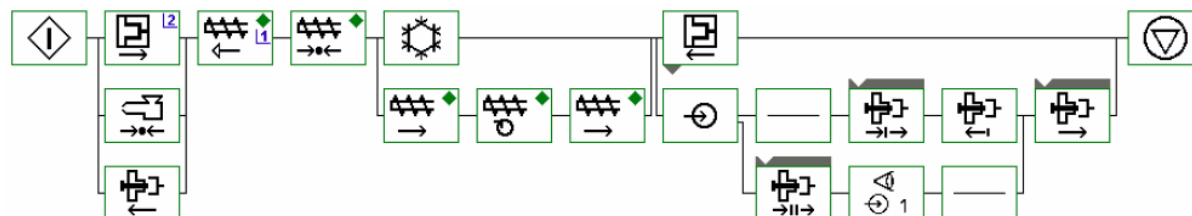
用于快速成型的高速机 – ARBURG H IMM for Fast Cycle – ARBURG H

ARBURG

支持主副轴同时动作的强大控制系统

Powerful Man-Machine-Interface & control system, simultaneous movements of main and sub-axis

ALLROUNDER 520 H 1500-800



循环周期/cycle	[s]	6.5
小时塑化功率 Throughput	[kg/h]	19.5
注塑压力 Injection Pressure	[bar]	765

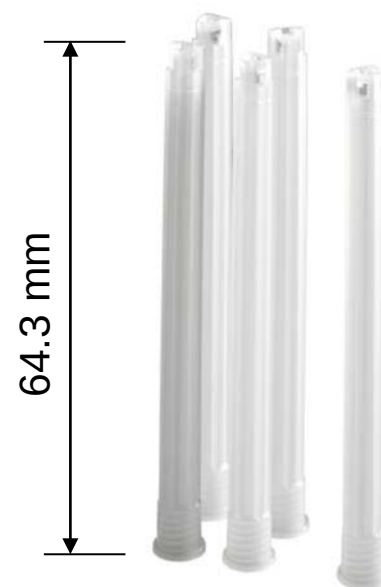
模腔/Cav	32
产品单重/Weight	1.1 [g]
材料/Material	PP

用于快速成型的高速机 – ARBURG H IMM for Fast Cycle – ARBURG H

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ALLROUNDER 470 H 1000-400

循环周期/Cycle	[s]	5.2
小时塑化功率 Throughput	[kg/h]	15.3
注射时间 Injection Time	[s]	0.3
注塑压力 Pressure	[bar]	1600

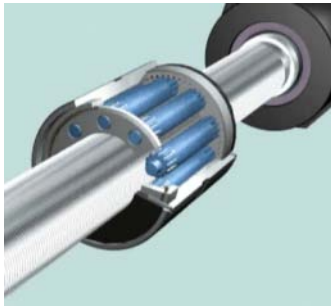


模腔/Cav	32
产品单重 Part Weight	0.46 [g]
材料/Material	HDPE

用于快速成型的高速机 – ARBURG H IMM for Fast Cycle – ARBURG H



- 运行成本/Operation Cost
 - 高性价比的德国原产备件
 - High price-efficiency ration made in Germany spare parts
 - 高性能钢材 – 坚固耐用，适用于高速短周期注塑
 - High quality steel – for fast cycle application, robust,
 - 使用多个行星丝杆，增大接触面积，从而加大承载能力，增强抗冲击能力，高加-减速，使用寿命长
 - planetary spindle, high load, impact resistant, high acceleration, long life



用于快速成型的高速机 – ARBURG H IMM for Fast Cycle – ARBURG H



模具 Mold	腔数 Cav	ARBURG机型 Machine Type
针筒/Barrel	48-32	570H2000-1300
针筒/Barrel	96	920H5000-3200
推杆/Plunge	48	570H2000-1300
保护套 Protector	64	470H1000-400
针头座 Needle Base	96	520H1500-800

可选射台/IU to select

400 (35/40/45) , 800 (45/50/55) ,
1300 (55/60/70) ,3200 (60/70/80)

射台根据产品重量及循环周期-塑化功率决定！

Cycle time & throughput -> IU size

建议配置一览 recommended options

- 水冷/water cooling
- 高耐磨分离式螺杆/High wear resistant
- 高塑化功率/high throughput
- 整流罩/flow box
- 动能回收/kinetic energy recycle
- 主副轴同时动作/simultaneous movement of main & sub axis
- 大功率顶出/strong ejector
- 顶出和开模同步/synchronized ejection and mold opening
- 氮气蓄能器注射/injection by accumulator
- 支持叠模（液压抽芯等）/core pulls for stack mold
- 不锈钢分拣料斗/stainless sort unit
- 封闭式传送带/close conveyer belt
- 高机脚/increased height of machine base

周边设备及自动化

Peripherals & Automation



- 粘针机/Needle Glue Machine - 针头座和针尖钢件的粘结/Glue needle & base together
国产/local: 200k - 400k/天/day (200k - 700k人民币/RMB)
- 组装机/assembly - 注射器的组装/assemble parts to syringes
国产/local: 250 - 300/分钟/min (150k人民币/RMB)
韩国/Korean: 400k人民币/RMB
德国/Germany: 800 - 1k/分钟/min (上百万人民币/several millions RMB)
- 印刷机 /Printer - 在注射器上印刷刻度等/print the scale/logo on the syringe
- 包装机/packing machine - 将注射器封装入半透膜/pack the syringe with semi-permeable foil (DuPont)
- 净化室/Decontamination Room - 环氧乙烷/epoxy-ethane, 钴60放射/Co60 Radiation



医用塑料产品的注塑方案

Medical Applications by Injection Molding

ARBURG



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