QUADRANT – Engineering Plastic Products

MediTECH Product Line – implantable grade UHMW-PE

Stefan Willing, QUADRANT

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QUADRANT MediTECH

MediTECH® MEDICAL POLYMERS

Medical grade UHMW-PE manufactured and supplied by Quadrant MediTECH as shapes (plate, rod, preforms) to be used in Orthopedics Implants

CHIRULEN®
EXTRULEN®
PE-UHMW
medical grade

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EXTRULEN®
PE-UHMW
medical grade

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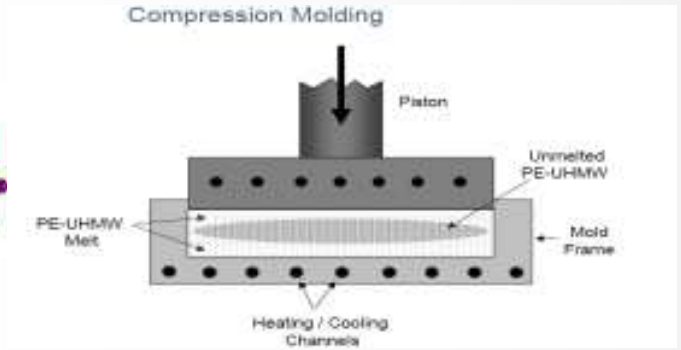
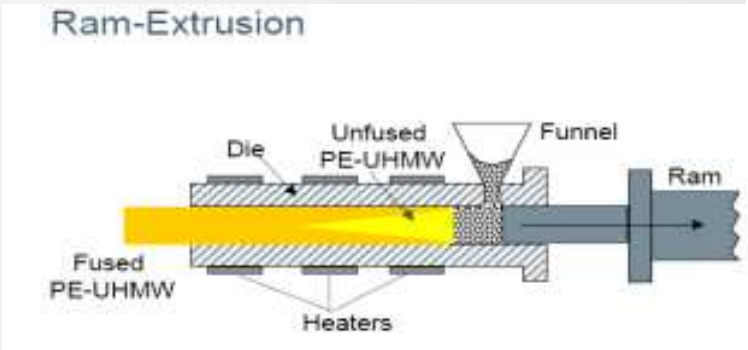
QUADRANT MediTECH: Medical grade UHMW-PE

Ticona ENGINEERING POLYMERS

GUR 1020 and GUR 1050 resin (powder)

MediTECH MEDICAL POLYMERS





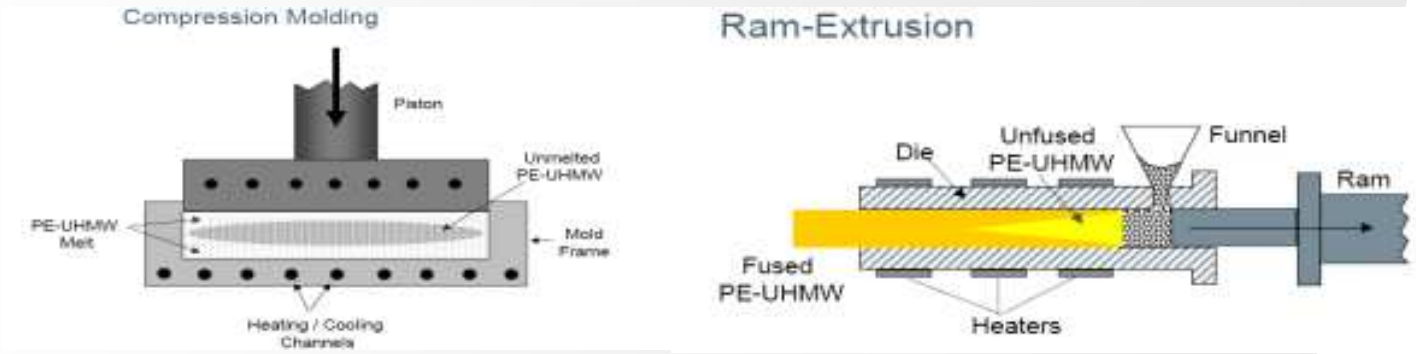
CHIRULEN® 1020 and 1050 **EXTRULEN® 1020 and 1050**

Shapes (plates, rods, preforms)

smith&nephew WRIGHT. ORCHID MACDEE ORTHOPEDIC SOLUTIONS SYNTHES® zimmer stryker B BRAUN SHARING EXPERTISE accellent Corin LINK DePuy a Johnson & Johnson company DJO surgical BIOMET QUADRANT

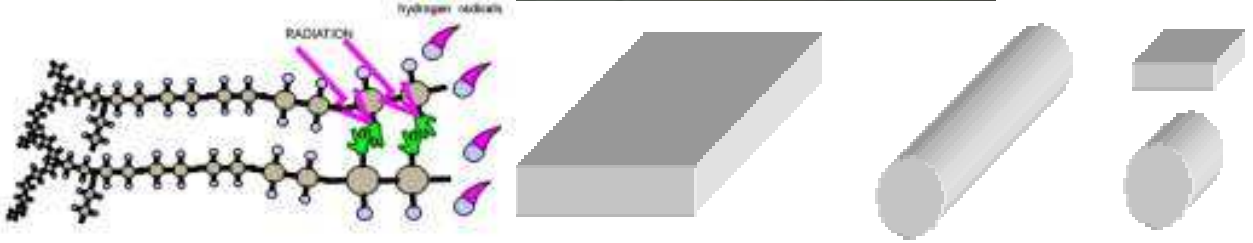
QUADRANT MediTECH: Medical grade UHMW-PE

Primary Conversion & Resin Conditioning



Post-sintering and Annealing Processes

Cross-linking Expertise



Blending & Mixing Technology

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QUADRANT MediTECH: Medical grade UHMW-PE

Compression molding technology: 3 dedicated presses

Cleanroom operations (ISO 14644-1, class 8, note: Vreden only)

Special mold surface allows elimination of release agent

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MediTECH Conversion Technology

- **Fort Wayne Pressing Operation**

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Product range of CHIRULEN® and EXTRULEN®

- **CHIRULEN® 1020**
- **CHIRULEN® 1050**

standard sizes:

sheet size	1000 mm x 500 mm
sheet thickness	20 mm to 80 mm
rod diameter	20 mm to 80 mm
rod length	500 mm, 1000 mm

- **EXTRULEN® 1020**
- **EXTRULEN® 1050**

standard diameter	12 mm to 100 mm
length	500 mm, 1000 mm, 3000 mm

Special sizes, cut-to-size, fabricated preforms upon request

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QUADRANT – Engineering Plastic Products

MediTECH Product Line – Typical applications

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[Orthopedics - Total Joint Replacement]

[Application: artificial hip and knee components]

Material	[CHIRULEN® 1020 and 1050]
Processes	[Compression Molding, Stabilization under N_2]

Properties and benefits:

- Stabilized / annealed under inert atmosphere (N_2)
- High dimensional stability
- Very high impact strength, excellent sliding properties, very high wear resistance
- Full traceability for 30 years
- GMP - Validated Processes
- Biocompatible, per ISO 5834, ASTM F 648 and USP Class VI requirements
- Long-term record in Orthopedics (e. g. hip, knee, elbow joint replacements)

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[Orthopedics - Total Joint Replacement]

[Application: artificial hip and knee components]

Material	[Crosslinked CHIRULEN® 1020/1050]
Processes	[Compression Molding, Stabilization under N_2, Crosslinking process, secondary stabilization process under N_2]

Properties and benefits:

- Improved wear resistance
- manufactured according to customer specifications
- cross-linking and stabilizing expertise with MediTECH, irradiation process performed by outside vendor(s)
- GMP - Validated Processes

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[Orthopedics – Spinal Implant]

[Application: discs in spinal implants]

Material	[CHIRULEN® 1020]
Processes	[Compression Molding, Stabilization under N_2]

Properties and benefits:

- High dimensional stability
- Very high toughness and wear resistance
- Full traceability for 30 years
- GMP - Validated Processes
- Biocompatible per USP Class VI requirements

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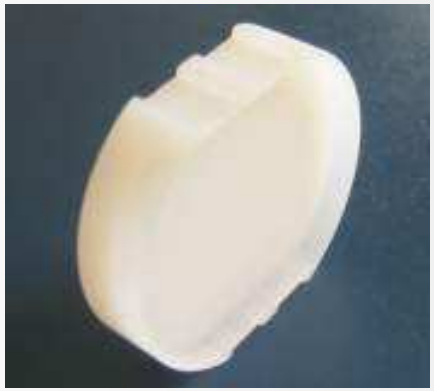
[Medical Devices]



[Application: cutting block for medical device]

Material	[CHIRULEN® 1020]
Processes	[Compression Molding, Stabilization under N_2]

Properties and benefits:

- High dimensional stability
- Very high toughness and wear resistance
- Full traceability for 30 years
- GMP - Validated Processes
- Biocompatible per USP Class VI requirements

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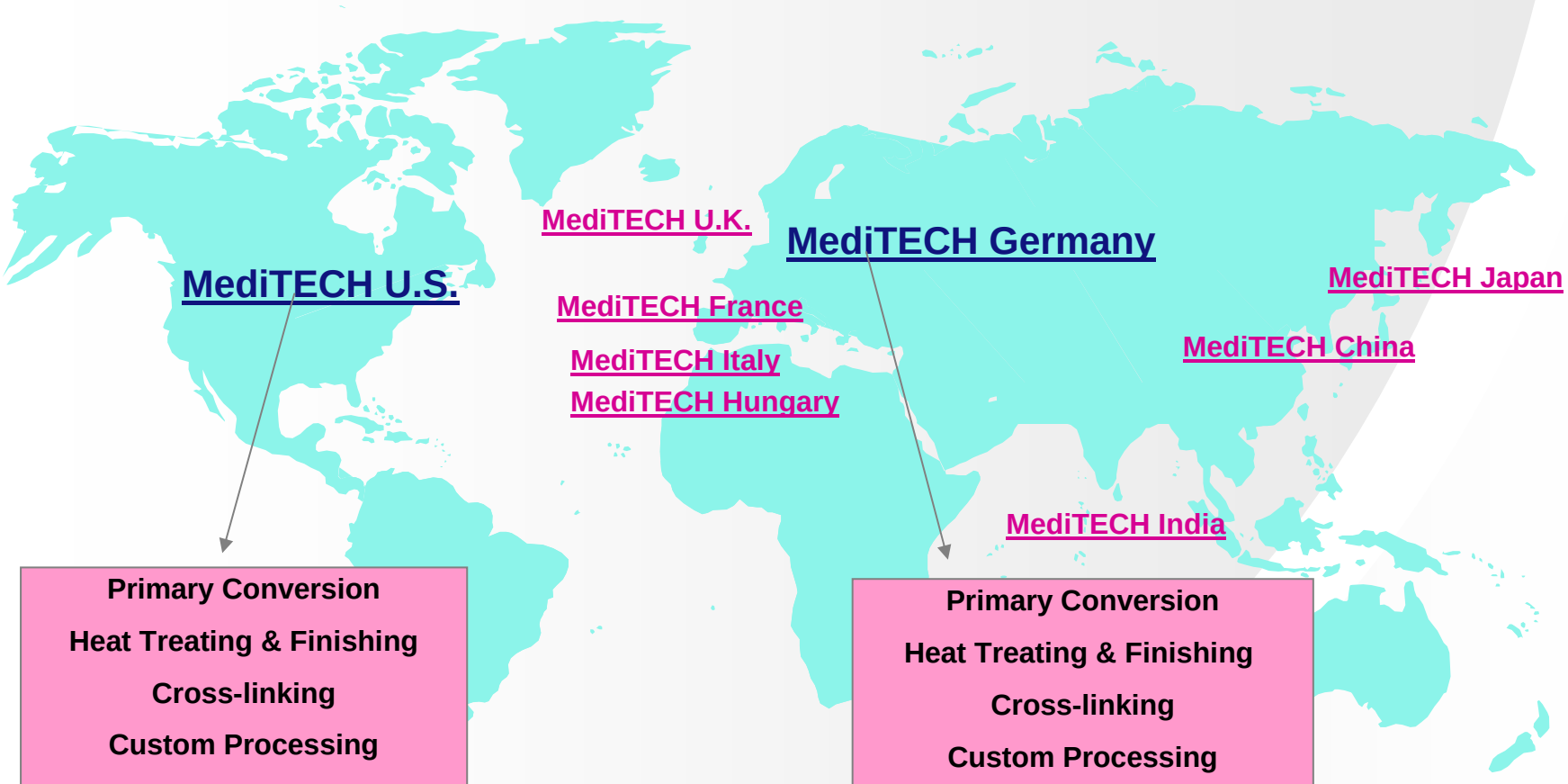
MediTECH® Product Line: Locations within Quadrant



Primary Conversion
Heat Treating & Finishing
Cross-linking
Custom Processing
Sales & Distribution
R&D / Testing Laboratory

Primary Conversion
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MediTECH® - Quality Management

- Quality Guidelines: ASTM F 648 and ISO 5834, customer's specification
- Resin lot qualification process
- Cross-check for physical/mechanical properties with Ticona (raw material supplier) and MediTECH U.S.
- Monthly resin lot verification and cross-check
- Dedicated MediTECH press operation since 1994
- 100 % press cycle verification
- Validated compression molding process
- Validated annealing cycles (nitrogen atmosphere)
- AQL10 - visual inspection
- ISO 9001 certified
- ISO 14001 certified
- ISO 13485 certified

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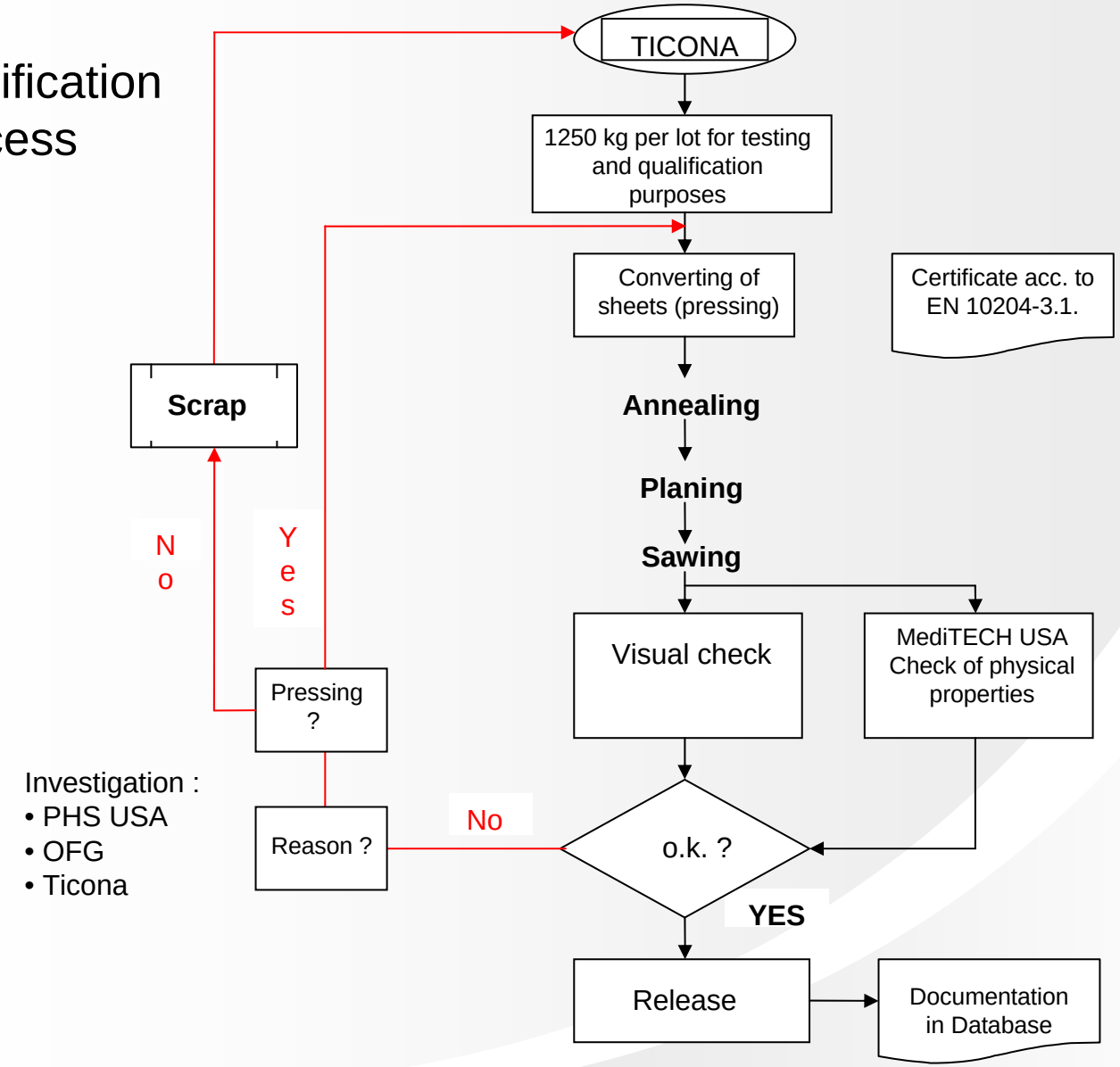
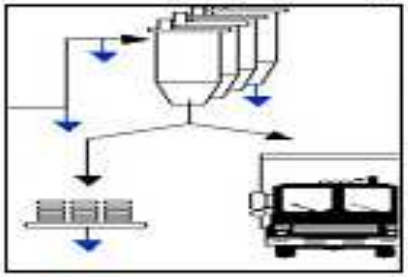
MediTECH® - Quality Management

Lot Qualification Process



MediTECH Traceability System

GUR Production (UHMW-PE) at Ticona



Ticona Resinlot: 120.000-150.000 kg
Lot-No.: **74883**

Shipment to Vreden: 40.000-50.000 kg
Shipment to MediTECH US: 40.000-50.000 kg

Compression molding of the resin in Vreden at #12

1. sheet, 2x1m Press Position No. **2003 285 o**

2. sheet, 2x1m Press Position No. **2003 285 ■**

3. sheet, 2x1m Press Position No. **2003 285 ▪**

Machining of parts:

During the manufacturing, based on the pressed sheets, every part gets his own identification number. We can refere all relevant data during production (resin lot, press and annealing cycle,...) back to the part.

Sheet, 1000x500mm
Rod
Cut-to-size
Preforms
Finished part

Identification-No. **20033976**

- **Process parameters are visualized and filed during the entire process**
- **Quality Manuals available in the Intranet for medical personnel**
- **Traceability System based on Electronic Database**

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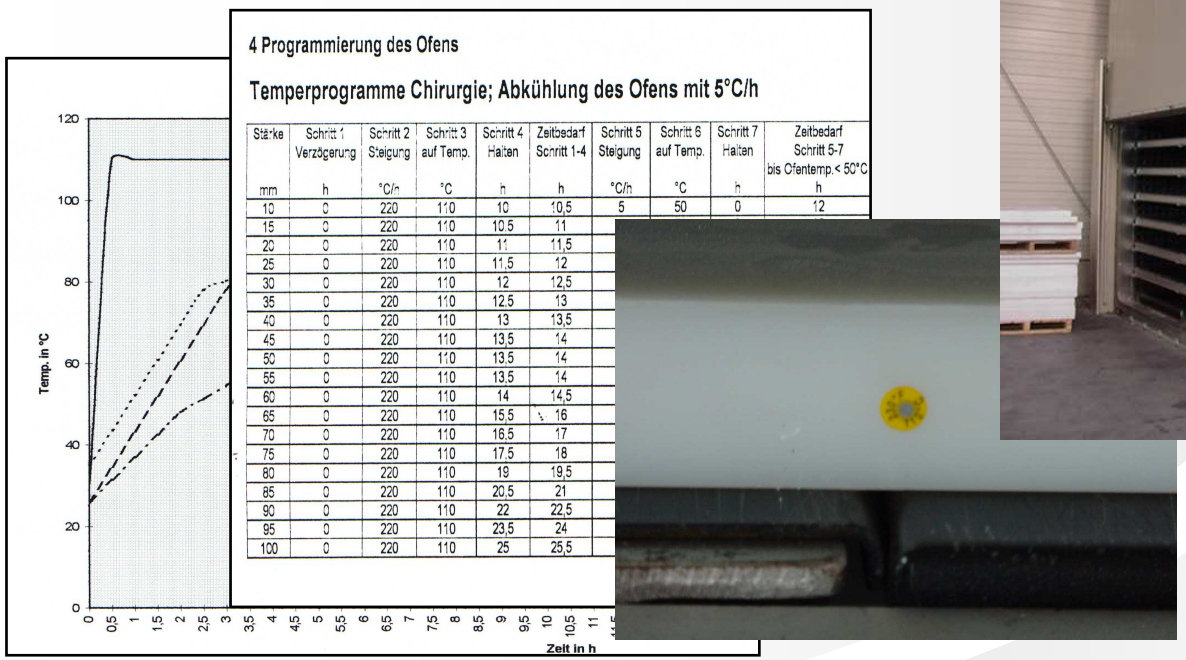
MediTECH® - Technology

- **Annealing Technology using Nitrogen Atmosphere**
  - **Tight implant tolerances**
  - **preventing material oxidation**
  - **Quenching free radicals after cross linking**



4 Programmierung des Ofens

Temperprogramme Chirurgie; Abkühlung des Ofens mit 5°C/h

Stärke	Schritt 1 Verzögerung	Schritt 2 Steigung	Schritt 3 auf Temp.	Schritt 4 Halten	Zeitbedarf Schritt 1-4	Schritt 5 Steigung	Schritt 6 auf Temp.	Schritt 7 Halten	Zeitbedarf Schritt 5-7 bis Ofentemp.< 50°C
mm	h	°C/h	°C	h	h	°C/h	°C	h	h
10	0	220	110	10	10,5	5	50	0	12
15	0	220	110	10,5	11				
20	0	220	110	11	11,5				
25	0	220	110	11,5	12				
30	0	220	110	12	12,5				
35	0	220	110	12,5	13				
40	0	220	110	13	13,5				
45	0	220	110	13,5	14				
50	0	220	110	13,5	14				
55	0	220	110	13,5	14				
60	0	220	110	14	14,5				
65	0	220	110	15,5	16				
70	0	220	110	16,5	17				
75	0	220	110	17,5	18				
80	0	220	110	19	19,5				
85	0	220	110	20,5	21				
90	0	220	110	22	22,5				
95	0	220	110	23,5	24				
100	0	220	110	25	25,5				

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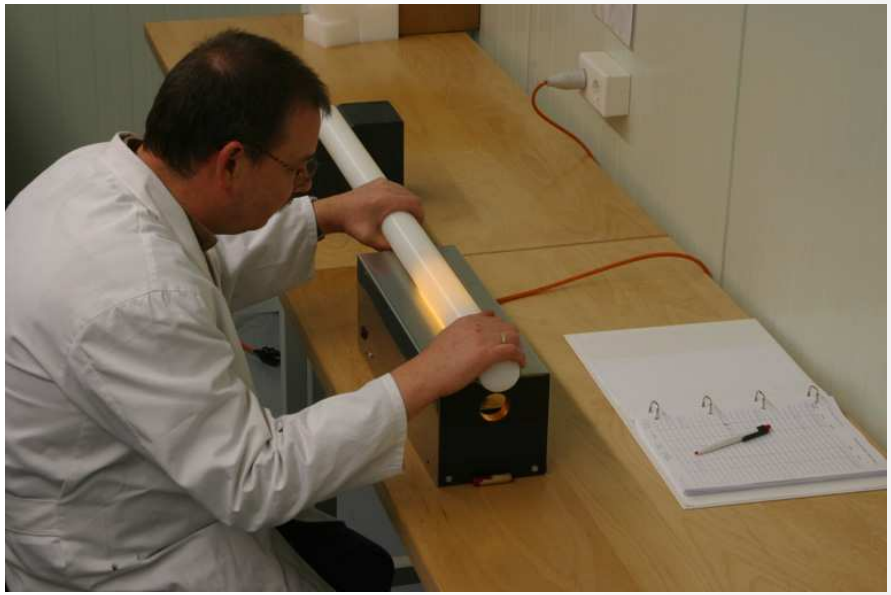
MediTECH® - Quality Management

How does MediTECH Division ensure the extremely high quality standard necessary for CHIRULEN® and EXTRULEN® ?



CHIRULEN® and EXTRULEN® products undergo intensive visual inspection to make sure requirements of ISO 5834 and ASTM F 648 are by far exceeded.

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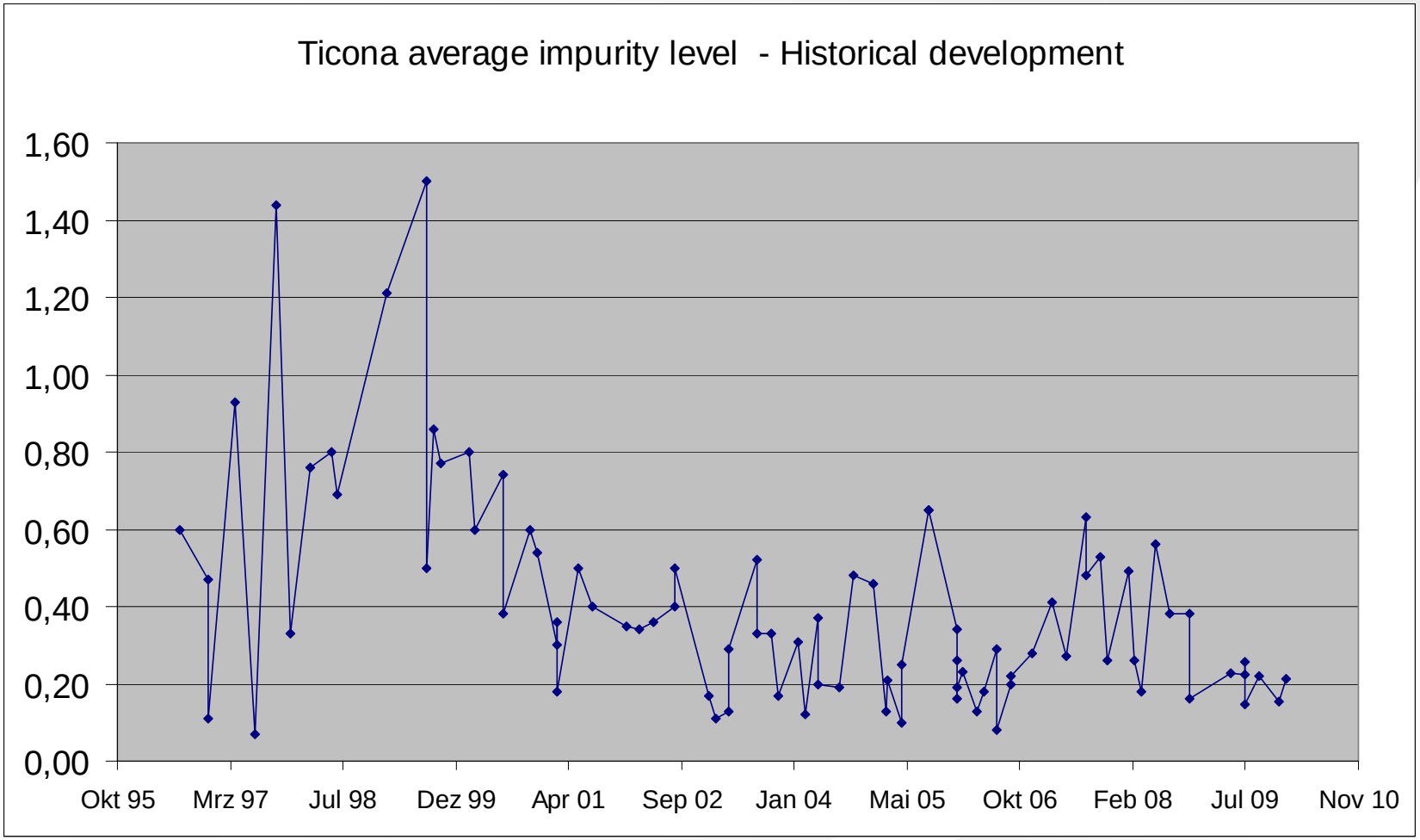
Resin “Cleanliness”

Test per ISO 5834-1 and ASTM F-648 at Ticona

7.1.2.1 A 300 g sample is divided into four 75 g samples. Place a 75 g sample in each of four 1000 mL Erlenmeyer flasks, add 400 mL isopropyl alcohol, shake 5 min, and let settle for 5 min. Count the total number of particles of extraneous matter in the four flasks.



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Shape “Cleanliness”

Test per ISO 5834 -2 and ASTM F-648 at QEPP MediTECH

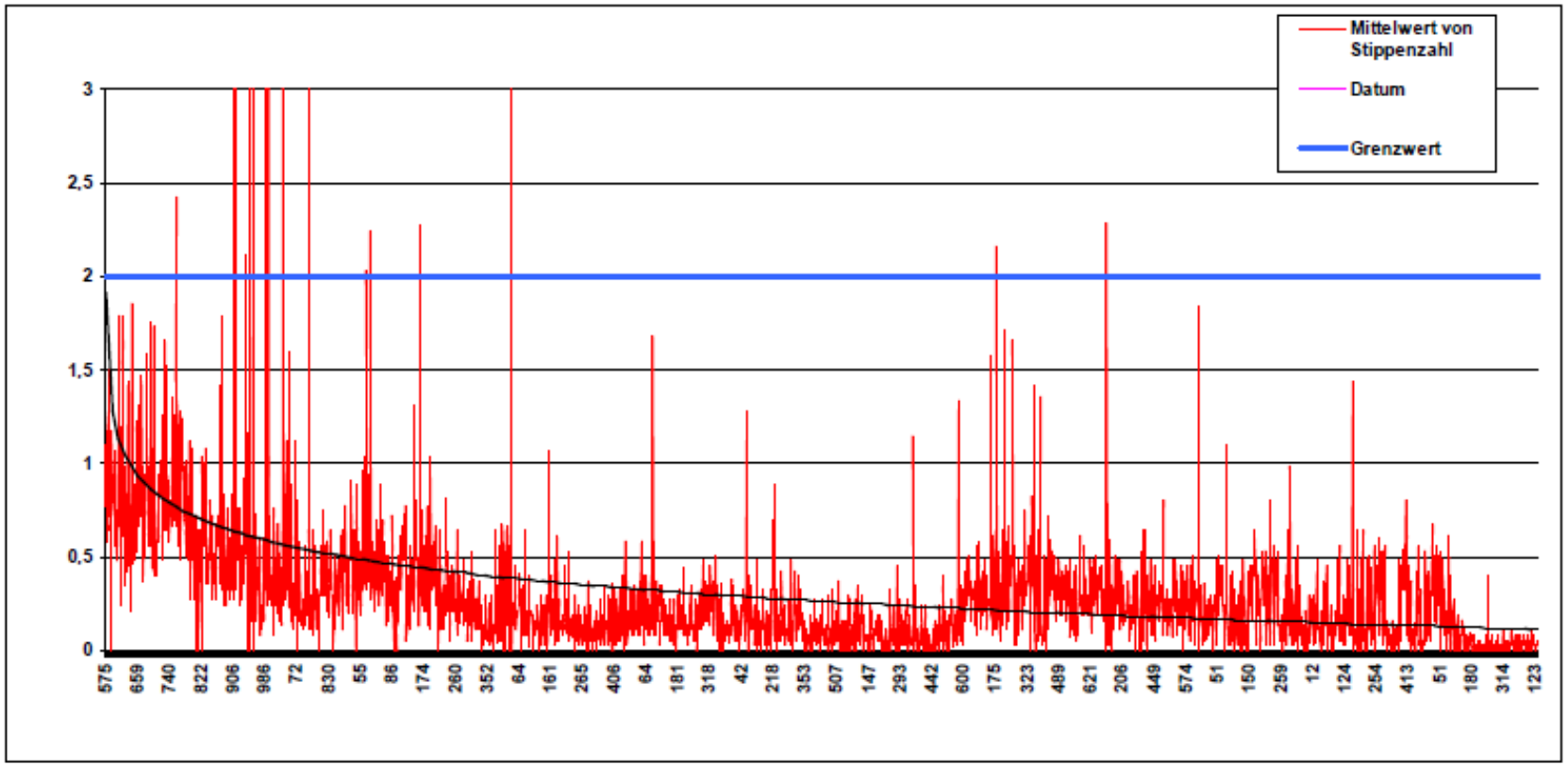
8.8 Sample area for extraneous matter

A total machined surface area of (500×10^3) mm^2 shall be taken from locations within the fabricated form. The area examined shall include both transverse and longitudinal samples or may be produced by repeated sectioning through the thickness of fabricated form.

Chirulen Pressenposition - Stippenzahl

Presse: 12

von: 01.01.1998 bis: 21.04.2010



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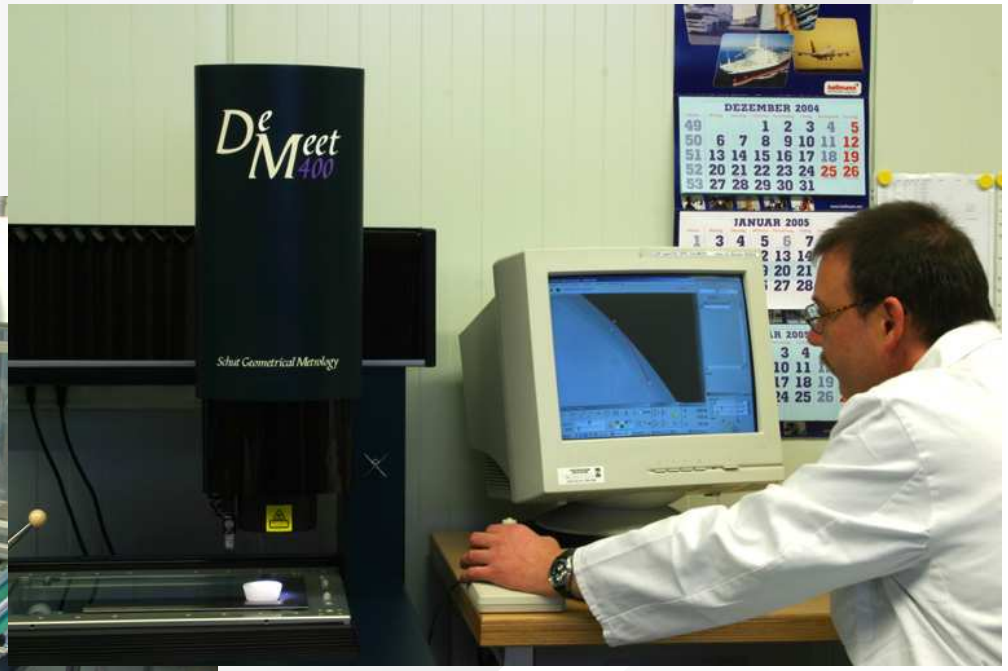
MediTECH® - Technology

State of the art machining operations

- CNC lathe without cooling agent (for preforms only – no final implant component!)
- Optical and mechanical measurement device
- AQL10 optical inspection



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MediTECH® - Technology

Quality standards achieved by:
-> continuous process improvements and well trained people

resin →	pressing →	annealing →	Machining (preforms)
▪ Resin lot qualification and Cross-check process • Reduced contamination by training the operators • Validated resin conditioning	• Dedicated press • Small scale press • High pressure operations • No release agents ▪ Validated in the manner of GMP	• Cycle for dimensional stability, low stress • Unique inert process, prevent oxidation	• No cooling agents • Special tooling and machining parameters • Optical inspection of surface quality

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Process/Product Innovation

Proven Research and Development capabilities

MediTECH® conversion evolution

- **Next generation pressing technology for product and process improvement**
- **Improved homogeneity through optimized resin handling**

Radiation processing (Crosslinking)

- **Developed jointly with our customers' R&D / Technical Departments**
- **Leading supplier of Crosslinked UHMWPE in bulk form Radiation processing (Crosslinking)**

Stabilized PE-UHMW

- **Blend PE-UHMW with additives, to improve oxidation behavior**
- **Developed jointly with our customers' R&D / Technical Departments**

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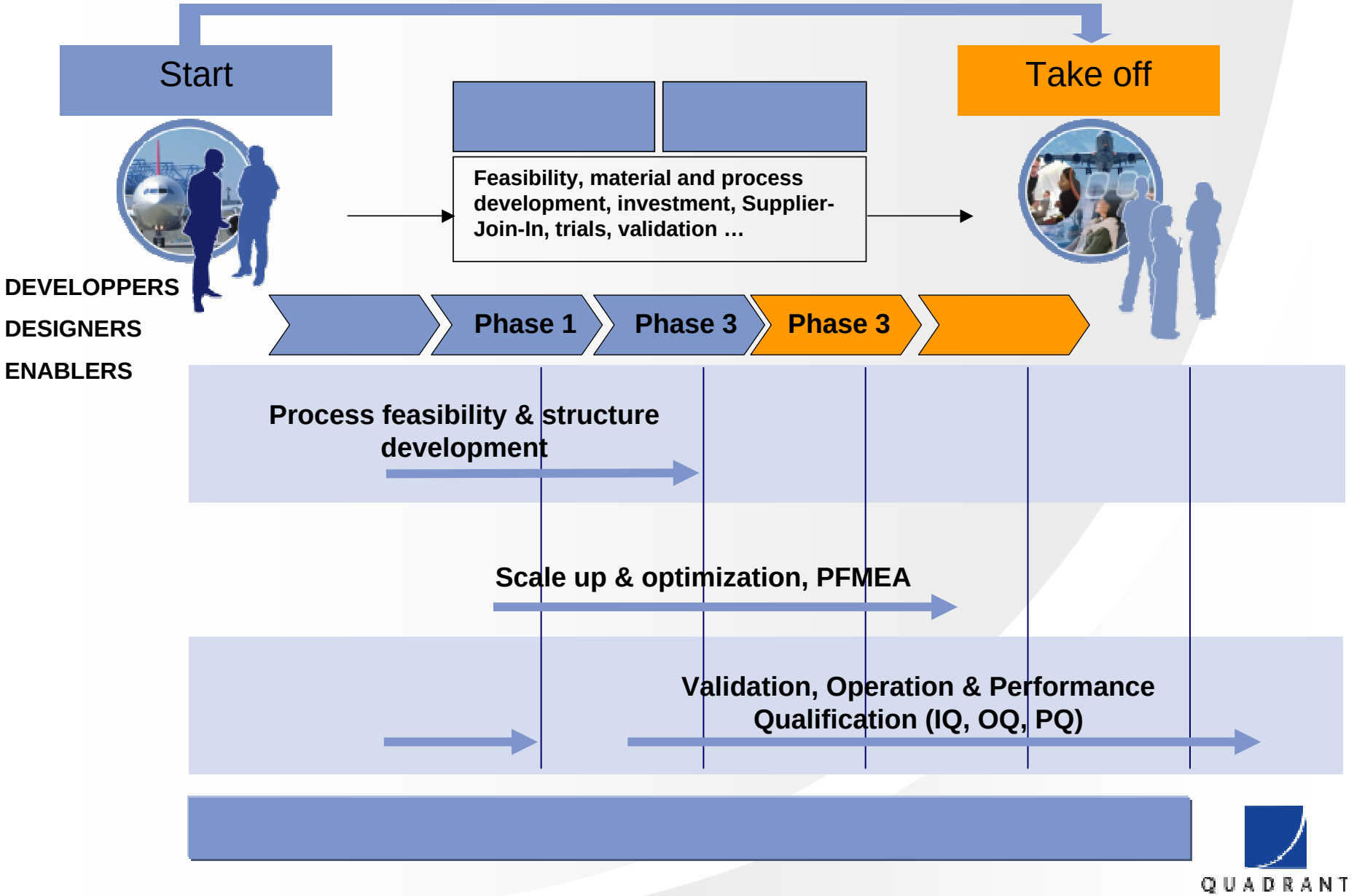
Jointly developed Medical Polymers: UHMW-PE with Vitamin E



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Cross-linking of medical grade PE-UHMW

Highly cross-linked medical grade PE-UHMW

Latest development in the orthopedic implant industry with regard to Polyethylene:

- **Highly cross-linked PE-UHMW with improved tribological properties.**
- **Highly cross-linking achieved through either electron beam or gamma irradiation and subsequent, specially designed, annealing process to eliminate free radicals.**
- **…to markedly improve the wear resistance of UHMWPE**
- **…to significantly reduce the number of wear particles generated in vivo.**

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Cross-linking of medical grade PE-UHMW

Radiation Chemistry

- Gamma Irradiation
- E-Beam Irradiation

Conventional Chemistry

- Peroxide Chemistry
- Silane Chemistry

Radiation Units: 10 kGy = 1 Mrad

Typical sterilization dose levels: 25-40 kGy = 2.5-4 Mrad

Highly cross-linking: above typical dose level of sterilization.

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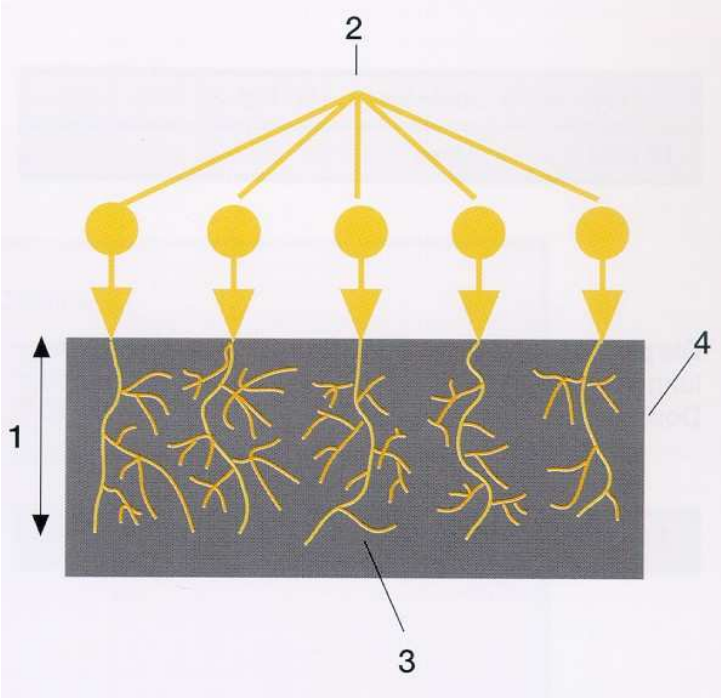
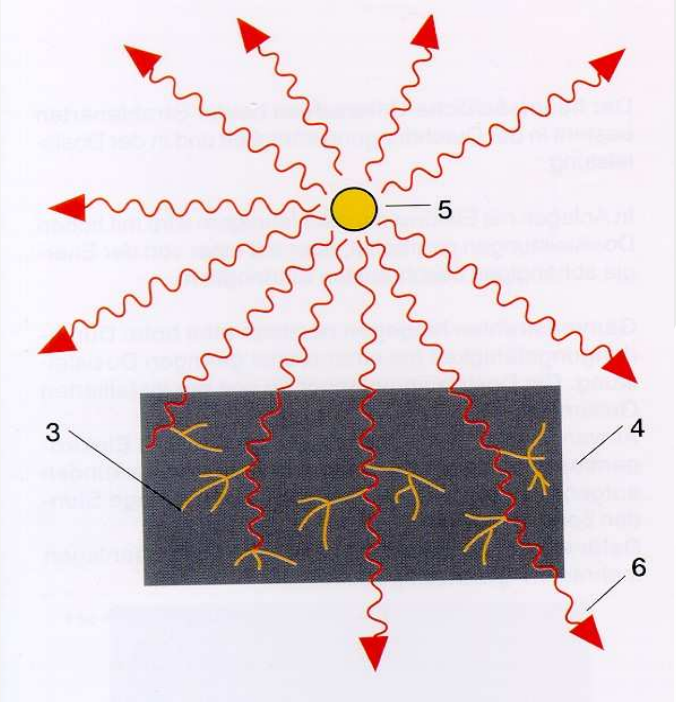
E-beam and gamma irradiation

E-beam irradiation



Gamma irradiation



1 - penetration depth of electrons

2 - primary electrons (source)

3 - secondary electrons

4 - irradiated material

5 - Co-60 irradiation source

6 - γ-quanta

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Cross-linking of medical grade PE-UHMW

What can MediTECH contribute to develop highly cross-linked PE-UHMW for orthopedic implants?

- ✓ **MediTECH has several years experience developing highly cross-linked PE-UHMW for orthopedic implants in close cooperation with leading orthopedic implant manufacturers**
- ✓ **MediTECH currently provides significant commercial quantities of radiation cross-linked PE-UHMW to the orthopedic industry**
- ✓ **MediTECH understands the radiation process with respect to PE-UHMW closely cooperating with radiation vendors**
- ✓ **MediTECH knows how radiation and subsequent annealing affects PE-UHMW**
- ✓ **MediTECH has more than 20 years experience heat treating PE-UHMW for stabilization on large scale**

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Cross-linking of medical grade PE-UHMW

Supply chain for highly cross-linked premium PE-UHMW

1. **MediTECH produces semi-finished PE-UHMW products (CHIRULEN® and EXTRULEN®)**
2. **Irradition of PE-UHMW semi-finished products at irradiation vendor at specified dose range (note: the dose range is to be specified by the OIM)**
3. **Specially designed annealing process at MediTECH to eliminate residual free radicals and to complete cross-linking process (note: annealing temperature and process is to be specified by the OIM)**
4. **Machine finish of highly cross-linked PE-UHMW products (planed sheets, rods, preforms etc.) at MediTECH**
5. **Delivery to customer, machine finish, packaging, sterilization**

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Options for highly cross-linked premium PE-UHMW

Example for a process specification to be devised by the Impant Manufacturer

Step					
1	**base material**		Chirulen 1020/1050	CHIRULEN 1020	
2	**shape**	**initial size**	sheet 1000x500 [mm] x		[mm]
		at irradiation	rod 1000 [mm] x	70	[mm]
3	**irrdiation**		gamma, dose rate	75	[kGy], Tolerance: +/- 10 %
			e-beam, dose rate		[kGy]
			Temperature	room temperature	[℃]
			Atmosphere (Air/Inert)	Air	
4	**quenching**		MediTECH cycle	150	[℃]
			110°/ 150 °		
			Atmosphere (Air/Inert)	Inert (= Nitrogen)	
5	**remove surface**	**final shape**	sheet 1000x500 [mm] x		[mm]
		after irradiation and annealing/quenching	rod 1000 [mm] x	60	[mm]
6	**packaging**		standard/ black PE film	black PE film	

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