

Standard harm. under	Standard	Title	Sections of the Annex
		<p>Teil 5: Prüfungen auf In-vitro-Zytotoxizität (Part 5: Tests for in vitro cytotoxicity);</p> <p>Teil 6: Prüfungen auf lokale Effekte nach Implantationen (Part 6: Tests for local effects after implantation);</p> <p>Teil 7: Ethylenoxid-Sterilisationsrückstände (Part 7: Ethylene oxide sterilization residuals);</p> <p>Teil 9: Rahmen zur Identifizierung und Quantifizierung von möglichen Abbauprodukten (Part 9: Framework for identification and quantification of potential degradation products);</p> <p>Teil 10: Prüfungen auf Irritation und Hautsensibilisierung (Part 10: Tests for irritation and skin sensitization);</p> <p>Teil 11: Prüfungen auf systemische Toxizität (Part 11: Tests for systemic toxicity);</p> <p>Teil 12: Probenvorbereitung und Referenzmaterialien (Part 12: Sample preparation and reference materials);</p> <p>Teil 13: Qualitativer und quantitativer Nachweis von Abbauprodukten in Medizinprodukten aus Polymeren (Part 13: Identification and quantification of degradation products from polymeric medical devices);</p> <p>Teil 14: Qualitativer und quantitativer Nachweis von keramischen Abbauprodukten (Part 14: Identification a. quantification of degradation products from ceramics);</p> <p>Teil 15: Qualitativer und quantitativer Nachweis von Abbauprodukten aus Metallen und Legierungen (Part 15: Identification a. quantification of degradation products from metals a. alloys);</p> <p>Teil 16: Entwurf und Auslegung toxikokinetischer Untersuchungen hinsichtlich Abbauprodukten und herauslösbaren Bestandteilen (Part 16: Toxicokinetic study design for degradation</p>	

Standard harm. under	Standard	Title	Sections of the Annex
		products and leachables); Teil 17: Nachweis zulässiger Grenzwerte für herauslösbare Bestandteile (Part 17: Establishment of allowable limits for leachable substances); Teil 18: Chemische Charakterisierung von Werkstoffen (Part 18: Chemical characterization of materials);	
93/42/EEC	DIN EN ISO 11135-1	Sterilisation von Produkten für die Gesundheitsfürsorge — Ethylenoxid — (Sterilization of health care products - Ethylene oxide) Teil 1: Anforderungen an die Entwicklung, Validierung und Lenkung der Anwendung eines Sterilisationsverfahrens für Medizinprodukte (Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices) <i>(planned to be replaced by DIN EN ISO 11135)</i>	1.3, 1.4, 2.2.5
	DIN ISO/TS 11135-2	Sterilisation von Produkten für die Gesundheitsfürsorge — Ethylenoxid — (Sterilization of health care products - Ethylene oxide) Teil 2: Leitfaden zur Anwendung von ISO 11135-1 (Part 2: Guidance on the application of ISO 11135-1) (Attention: Technical specification) <i>(planned to be replaced by DIN EN ISO 11135)</i>	1.3, 1.4, 2.2.5
93/42/EEC (other than Part 3) 90/385/EEC (other than Part 3)	DIN EN ISO 11137	Sterilisation von Produkten für die Gesundheitsfürsorge — Ethylenoxid — (Sterilization of health care products - Radiation) Teil 1: Anforderungen an die Entwicklung, Validierung und Lenkung der Anwendung eines Sterilisationsverfahrens für Medizinprodukte (Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices); Teil 2: Festsetzung der Sterilisationsdosis (Part 2:	1.3, 2.2.5

Standard harm. under	Standard	Title	Sections of the Annex
		Establishing the sterilization dose); Teil 3: Anleitung zu dosimetrischen Aspekten (Part 3: Guidance on dosimetric aspects)	
93/42/EEC (only Part 2 and Part 3) 90/385/EEC (only Part 2 and Part 3)	DIN EN ISO 11138	Sterilisation von Produkten für die Gesundheitsfürsorge — Biologische Indikatoren (Sterilization of health care products - Biological indicators) Teil 1: Allgemeine Anforderungen (Part 1: General requirements); Teil 2: Biologische Indikatoren für Sterilisationsverfahren mit Ethylenoxid (Part 2: Biological indicators for ethylene oxide sterilization processes); Teil 3: Biologische Indikatoren für Sterilisationsverfahren mit feuchter Hitze (Part 3: Biological indicators for moist heat sterilization processes); Teil 4: Biologische Indikatoren für Sterilisationsverfahren mit Heißluft (Part 4: Biological indicators for dry heat sterilization processes); Teil 5: Biologische Indikatoren für Sterilisationsverfahren mit Niedertemperatur- Dampf-Formaldehyd (Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes) <i>(see also DIN EN ISO 18472)</i>	1.3, 1.4, 2.2.5
93/42/EEC (only Part 1 and Part 3) 90/385/EEC (only Part 1)	DIN EN ISO 11140	Sterilisation von Produkten für die Gesundheitsfürsorge — Chemische Indikatoren (Sterilization of health care products - Chemical indicators) Teil 1: Allgemeine Anforderungen (Part 1: General requirements); Teil 3: Indikatorsysteme der Klasse 2 zur	1.3, 1.4, 2.2.5, 2.2.6

Standard harm. under	Standard	Title	Sections of the Annex
		Verwendung im Bowie-Dick-Dampfdurchdringungstest (Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test); Teil 4: Indikatoren der Klasse 2, die alternativ zum Bowie- Dick-Test für den Nachweis der Dampfdurchdringung verwendet werden (Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration) <i>(see also DIN EN 867-5 and DIN EN ISO 18472)</i>	
93/42/EEC 90/385/EEC	DIN EN ISO 11737-1	Sterilisation von Medizinprodukten — Mikrobiologische Verfahren — (Sterilization of medical devices — Microbiological methods) Teil 1: Bestimmung der Population von Mikroorganismen auf Produkten (Part 1: Determination of a population of microorganisms on products)	1.2
93/42/EEC 90/385/EEC 98/79/EC	DIN EN ISO 11737-2	Sterilisation von Medizinprodukten — Mikrobiologische Verfahren — (Sterilization of medical devices — Microbiological methods) Teil 2: Prüfungen der Sterilität bei der Definition, Validierung und Aufrechterhaltung eines Sterilisationsverfahrens (Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process)	1.2
93/42/EEC 90/385/EEC 98/79/EC	DIN EN ISO 13485	Medizinprodukte — Qualitätsmanagementsysteme — Anforderungen für regulatorische Zwecke (<i>Zertifizierung</i>)(Medical devices - Quality management systems - Requirements for regulatory purposes)	1.3 1.2 1
	DIN EN ISO 14161	Sterilisation von Produkten für die Gesundheitsfürsorge — Biologische Indikatoren — Leitfaden für die Auswahl, Verwendung und Interpretation von Ergebnissen (Sterilization of health care products - Biological	1.3, 1.4, 2.2.5

Standard harm. under	Standard	Title	Sections of the Annex
		indicators - Guidance for the selection, use and interpretation of results)	
93/42/EEC 90/385/EEC 98/79/EC	DIN EN ISO 14937	Sterilisation von Produkten für die Gesundheitsfürsorge — Allgemeine Anforderungen an die Charakterisierung eines sterilisierenden Agens und an die Entwicklung, Validierung und Lenkung der Anwendung eines Sterilisationsverfahrens für Medizinprodukte (Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices) <i>(also applies to previously non-standardised methods)</i>	1.3, 1.4, 2.2 5
	DIN EN ISO 15882	Sterilisation von Produkten für die Gesundheitsfürsorge — Chemische Indikatoren — Leitfaden für die Auswahl, Verwendung und Interpretation von Ergebnissen (Sterilization of health care products - Chemical indicators - Guidance for selection, use and interpretation of results)	1.3, 1.4, 2.2 5
93/42/EEC (Part 1 and Part 2) 90/385/EEC (only Part 1)	DIN EN ISO 11607	Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte (Packaging for terminally sterilized medical devices) Teil 1: Anforderungen an Materialien, Sterilbarriersysteme und Verpackungssysteme (Part 1: Requirements for materials, sterile barrier systems and packaging systems); Teil 2: Validierungsanforderungen an Prozesse der Formgebung, Siegelung und des Zusammenstellens (Part 2: Validation requirements for forming, sealing and assembly processes) <i>(see also DIN ISO/TS 16775)</i>	1.3, 1.4, 2.2.4
93/42/EEC	DIN EN ISO	Sterilisation von Medizinprodukten — Vom	1.2, 2, 2.2 6

Standard harm. under	Standard	Title	Sections of the Annex
	17664	Hersteller bereitzustellende Informationen für die Aufbereitung von resterilisierbaren Medizinprodukten (Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices)	
93/42/EEC 90/385/EEC	DIN EN ISO 17665-1	Sterilisation von Produkten für die Gesundheitsfürsorge — Feuchte Hitze (Sterilization of health care products — Moist heat) Teil 1: Anforderungen an die Entwicklung, Validierung und Lenkung der Anwendung eines Sterilisationsverfahrens für Medizinprodukte (Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices)	1.3, 1.4, 2.2.5
	DIN ISO/TS 17665-2	Sterilisation von Produkten für die Gesundheitsfürsorge — Feuchte Hitze (Sterilization of health care products — Moist heat) Teil 2: Leitfaden für die Anwendung von ISO 17665-1 (Part 2: Guidance on the application of ISO 17665-1) (Attention: Technical specification)	1.3, 1.4, 2.2 5
	DIN EN ISO 18472	Sterilisation von Produkten für die Gesundheitsfürsorge — Biologische und chemische Indikatoren — Prüfausrüstung (Sterilization of health care products - Biological and chemical indicators - Test equipment)	1.3, 1.4, 2.2.5
	DIN 58921	Prüfverfahren zum Nachweis der Eignung eines Medizinproduktsimulators bei der Dampf-Sterilisation — Medizinproduktsimulatorprüfung (Test method to demonstrate the suitability of a medical device simulator during steam sterilisation — Medical device simulator testing)	1.3, 1.4, 2.2.5
	DIN SPEC 58929	Betrieb von Dampf-Klein-Sterilisatoren im Gesundheitswesen — Leitfaden zur Validierung und Routineüberwachung der	1.3 1.4 2.2.5

Standard harm. under	Standard	Title	Sections of the Annex
		Sterilisationsprozesse (Operation of small steam sterilizers in the health-care system - Guidance for validation and routine control of sterilization processes)	
	DIN 58946-7	Sterilisation — Dampf-Sterilisatoren Sterilization — (Steam sterilizers) Teil 7: Bauliche Anforderungen und Anforderungen an Betriebsmittel (Part 7: Requirements on installation and services)	2.2.5
	DIN 58948-7	Sterilisation — Niedertemperatur-Sterilisatoren — (Sterilization - Low temperature sterilizers) Teil 7: Bauliche Anforderungen und Anforderungen an die Betriebsmittel sowie den Betrieb von Ethylenoxid-Sterilisatoren (Part 7: Requirements for the installation and operation of ethylene oxide sterilizers and their supply sources)	1.3, 1.4, 2.2 5
	DIN 58948-17	Sterilisation — Niedertemperatur-Sterilisatoren (Sterilization — Low temperature sterilizers) Teil 17: Bauliche Anforderungen und Anforderungen an die Betriebsmittel sowie den Betrieb von Niedertemperatur-Dampf-Formaldehyd-Sterilisatoren (Part 17: Requirements for the installation and operation of low temperature steam formaldehyde and formaldehyde sterilizers and their supply sources)	1.3, 1.4, 2.2 5
	DIN 58949	Desinfektion — Dampf-Desinfektionsapparate (Disinfection - Steam disinfection apparatus) Teil 1: Begriffe (Part 1: Terminology); Teil 2: Anforderungen (Part 2: Requirements); Teil 3: Prüfung auf Wirksamkeit (Part 3: Efficiency testing); Teil 4: Biologische Indikatoren zur Prüfung auf Wirksamkeit (Part 4: Biological indicators for efficacy tests); Teil 6: Betrieb von Dampf-Desinfektionsapparaten (Operating of steam disinfection apparatus);	1.3, 1.4, 2.2 2

Standard harm. under	Standard	Title	Sections of the Annex
		Teil 7: Bauliche Anforderungen und Anforderungen an die Betriebsmittelversorgung (Part 7: Structural requirements and requirements on service supply)	
	DIN 58952	<p>Sterilisation — Transportkörbe für Sterilbarrieresysteme (Sterilization - Transport baskets for sterile barrier systems)</p> <p>Teil 2: Sterilisierkörbe aus Metall (Part 2: Sterilizing baskets made of metal);</p> <p>Teil 3: Sterilisiersiebschalen für Sterilisiergut aus Metall (Part 3: Instrument trays for sterilizing goods made of metal)</p>	1.3, 1.4, 2.2.4, 2.2.5
	DIN 58953	<p>Sterilisation — Sterilgutversorgung (Sterilization - Sterile supply)(<i>Begriffe, Logistik von sterilen Medizinprodukten, Anwendungstechniken</i>)(<i>Terminology, logistics of sterile medical devices, methods of use</i>)</p> <p>Teil 1: Begriffe (Part 1: Terminology);</p> <p>Teil 6: Prüfung der Keimdichtigkeit von Verpackungsmaterialien für zu sterilisierende Medizinprodukte (Part 6: Microbial barrier testing of packaging materials for medical devices which are to be sterilized);</p> <p>Teil 7: Anwendungstechnik von Sterilisationspapier, Vliesstoffen, gewebten textilen Materialien, Papierbeuteln und siegelfähigen Klarsichtbeuteln und -schläuchen (Part 7: Use of sterilization paper, nonwoven wrapping material, textile materials, paper bags and sealable pouches and reels)</p> <p>Teil 8: Logistik von sterilen Medizinprodukten (Part 8: Logistics of sterile medical devices);</p> <p>Teil 9: Anwendungstechnik von Sterilisierbehältern (Part 9: Use of sterilization</p>	2.2 4 3

Standard harm. under	Standard	Title	Sections of the Annex
		containers)	
93/42/EEC	DIN EN 13795	Operationsabdecktücher, -mäntel und Rein-Luft-Kleidung zur Verwendung als Medizinprodukte, für Patienten, Klinikpersonal und Geräte — Allgemeine Anforderungen für Hersteller, Wiederaufbereiter und Produkte, Prüfverfahren und Gebrauchsanforderungen (Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment - General requirements for manufacturers, processors and products, test methods, performance requirements and performance levels)	
	DIN EN 15986	Symbol zur Kennzeichnung von Medizinprodukten — Anforderungen zur Kennzeichnung von phthalathaltigen Medizinprodukten (Symbol for use in the labelling of medical devices - Requirements for labelling of medical devices containing phthalates)	2.2.6

Annex B - Standardisation projects

Standard harm. under Dir.	Standardisati on projects	Title	Sections of the Annex
	E DIN 58946- 7	Sterilisation — Dampf-Sterilisatoren Sterilization — (Steam sterilizers) Teil 7: Bauliche Voraussetzungen sowie Anforderungen an die Betriebsmittel und den Betrieb von Dampf-Sterilisatoren im Gesundheitswesen (Part 7: Edifical preconditions, requirements for the services and the operation of steam sterilizers used in health care facilities) <i>(Scheduled to replace DIN 58946-7:2004)</i>	2.2.5
93/42/EEC	E DIN EN ISO	Medizinprodukte — Bei Aufschriften von	2.2.5

90/385/EEC 98/79/EC	15223-1	Medizinprodukten zu verwendende Symbole, Kennzeichnung und zu liefernde Informationen (Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied) Teil 1: Allgemeine Anforderungen (Part 1: General requirements) <i>(Scheduled to replace DIN EN 980)</i>	
	E DIN EN 15224	Dienstleistungen in der Gesundheitsversorgung — Qualitätsmanagementsysteme — Anforderungen nach EN ISO 9001:2008; Deutsche Fassung FprEN 15224:2012 (Health care services - Quality management systems - Requirements based on EN ISO 9001:2008; German version EN 15224:2012) <i>(Scheduled to replace DIN CEN/TS 15224:2006)</i>	1.3, 1.4, 2.2 2
93/42/EEC 90/385/EEC 98/79/EC	E DIN EN ISO 11135	Sterilisation von Produkten für die Gesundheitsfürsorge — Ethylenoxid — Anforderungen an die Entwicklung, Validierung und Lenkung der Anwendung eines Sterilisationsverfahrens für Medizinprodukte (Sterilization of health care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices) <i>(Scheduled to replace DIN EN ISO 11135-1 and DIN ISO/TS 11135-2)</i>	1.3, 1.4, 2.2 5
	DIN ISO/TS 16775	Verpackungen für in der Endverpackung sterilisierte Medizinprodukte — Leitfaden für die Anwendung von ISO 11607-1 und ISO 11607-2 (Packaging for terminally sterilized medical devices — Guidance for the Application of ISO 11607-1 und ISO 11607-2)	1.3 1.4, 2.2.4

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Links:

- FDA. Guidance on enforcement priorities for single-use devices reprocessed by third parties and hospitals.
(<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm107164.htm>) (<http://www.fda.gov/MedicalDevices/default.htm>)
- Device Bulletins and Hazard and Safety Notices der Medicines and Healthcare products Regulatory Agency (MHRA); Executive Agency of the Department of Health, UK.
(<http://www.mhra.gov.uk>)

Vanguard AG Product List

EP/Ablation	
メーカー名	製品名
Bard	Stinger, Scorpion
Biosense Webster	Celsius, EZ-Steer, Navi Star
Biotronik / VascoMed	AICath (Black, Blue, Cyan, Red, FullCircle)
Boston Scientific	Blazer Prime, Blazer II
Medfact	EasyCool
Medtronic	Conductr, Contactr, Enhancer, Marinr, Performr
Osyпка	Cerablato
St. Jude / Irvine Biomedical	Therapy, Livewire, Safire
Biosense Webster	Thermo Cool (Navi Star, Celsius, EZ-Steer, EZ-Steer NAV, SF, SF-NAV)
Boston Scientific	Chilli, Blazer Open Irrigated
Biotronik / VascoMed	AlCath Flux (Black, Blue, Green, Red, FullCircle, GeXtra)
Medtronic	Sprinklr
St. Jude / Irvine Biomedical	Therapy Cool Flex, Therapy Cool Path
EP Diagnostic	
メーカー名	製品名
Alcis	Dynamic
Bard	Dynamic, Orbiter, EP-XT, Radia
Biosense Webster	EZ Steer, Halo, Ismus Cath, Lasso, Lasso Nav, Parahisian, Webster
Biotronik / VascoMed	ViaCath, Lexx
Boston Scientific	Polaris, Blazer
Ela medical	Xtrem Dynamik
Medtronic	Soloist, Staplemapr, Torqr
Osyпка	Sirius
St. Jude / Irvine Biomedical	Reflexion Spiral, Inquiry, AFocus, Optima

EP Diagnostic fixed curve	
メーカー名	製品名
Bard	Viking, Tango
Biosense Webster	Avail, P-Supra, Webster
Biotronik / VascoMed	MultiCath, Woxx, Vascostim Pro
Boston Scientific	Explorer
Fiab	Spike
Medfact	EasyMap
Medtronic	Soloist, Torqr
Osyпка	Finder, Woxx
St. Jude / Irvine Biomedical	Inquiry, Supreme, Response
Carto 3	
メーカー名	製品名
Biosense Webster	Lasso NAV
Biosense Webster	Navi Star
Biosense Webster	Thermo Cool (Navi Star, EZ-Steer NAV, SF-NAV, SF-NAV Bi-Directional)
Medtronic / Ardian	Symplicity
Biosense Webster	HeartSpan
Cook	Endrys
Medtronic	Brockenbrough
St. Jude	BRK
Osyпка	Temporäre Ösophagus-Elektrode
St. Jude / Irvine Biomedical	Agilis
St. Jude / Irvine Biomedical	Fast Cath, Swartz
Ultrasound Catheter	
メーカー名	製品名
Biosense Webster	AcuNav
Siemens	AcuNav
St. Jude / Irvine Biomedical	ViewFlex, ViewFlex Xtra
Volcano	IVUS Eagle Eye (Gold, Platinum)

Surgical	
メーカー名	製品名
Olympus / Celon	Celon Pro Curve
Covidien / Autosuture	Endo Gia Universal
Ethicon Endo-Surgery	Endopath ETS 35, ETS 45
Covidien / Autosuture	Gia 60, 80
Ethicon Endo-Surgery	Proximate Linear Cutter TLC 55
Ethicon Endo-Surgery	Harmonic (ACE23E, ACE36E, ACE45E), Ultracision (LCSC5HA, CS14C, CS23C, LCSC5, LCSC5L)
PMI	Doro Schädeldorn
B. Braun / Aesculap	Orthopilot Passiv Marker
Northern Digital (NDI)	Passive Spheres
Orthosoft	Centerpuls Reflek
orto MAQUET	Centerpuls Reflek
biolitec	Megabeam
CeramOptec	ELVeS, Cerlas
Cook	Optilight
Cynosure	Smartlipo MPX
Dornier	Holmium, Standard-Lichtleiter SMA
KLS martin	Bare Fiber
Lumenis	Slimline
Medlight S.A.	Cylindrical Light Diffuser
Arthroscopy	
メーカー名	製品名
DePuy Mitek / Ethicon	VAPR-Elektroden
Ophthalmology	
メーカー名	製品名
Alcon	Straight Bipolar Brush
Alcon	Micro Tip, Turbo Sonics

Urology	
メーカー名	製品名
Mediplus	Zystometriekatheter
Medtronic	Urodynamik-Katheter
Porges	Selectip
Raumedic	Urobar
Rüsch	Cylindrical, Tiemann
UniSensor	UniTip
Wolf	Zystometriekatheter
W.O.M.	Mikro-Tip
biolitec	Laserlead
CeramOptec	Megabeam
Cook	OptiLite
Dornier	Holmium
Perimed	Peri-Flux
Cardiology Angiology Radiology	
メーカー名	製品名
Abbot Vascular	Viking
ACS / Guidant	Viking, Veripath
Boston Scientific	Runway, Mach 1
Braun	Serpia
Cordis	Vista Brite Tip, EnvoyXB
Medtronic	Launcher, Sherpa, Zuma, Z2
Merit Medical	Concierge
Vascular	Guide Liner
Spectranetics	Turbo Elite, Vitesse
Olympus / Celon	Celon Pro Curve
Medstim	Flowmeter Probe
Medtronic / Ardian	Symlicity
Advanced Vascular Dynamics	Compressar Disc
Anesthesia Intensive Care	
メーカー名	製品名
Kendall & Sheridan	Sheridan Spiral-Flex
Mallinckrodt	Broncho-Cath

Internal Medicine Endoscopy	
メーカー名	製品名
Boston Scientific	Jagwire, Jagtome, Dreamwire
Cook	Tracer Metro
Medwork	gSlider
Olympus	VisiGlide
Optimed	Black and White
Terumo	Radiofocus
Boston Scientific	Contour, Fluoro Tip
Cook	Classic ERCP Catheter
MTW Endoskopie	Standart, Filiform
Olympus	Startip, Füllkatheter
Olympus, Karl Storz, Richard Wolf, Pentax	Choledochoskope, Zystoskope, Uretero Renoskope, Video-Endoskope, Bronchoskope
Hitachi	Biopsy Attachment
MD Tech	Nadelführung f. Lorrax Stereo

見解 1

Dan Vukelich

President, AMDR

March 2, 2016

1 p.m. – 2 p.m.

Re-manufacturing has a long history in the U.S. and Germany and will begin in the UK and EU later this year. As you know, reimbursement in all of these markets is the same for both re-manufactured and OEM devices. The reason for this is that the devices are viewed as equivalent. In the early days, CMS issued guidance stating that reimbursement would be the same. One of the reasons for this was the desire to incentivize a practice that saves money for the healthcare system and reduces waste.

As you learned in your visit to the UK, the UK doesn't plan to initially allow the re-manufacturing of Class I devices. I think they will eventually change their minds on this as the EU plans to allow Class I re-manufacturing. The reason the UK has decided not to is that they don't currently have much significant oversight for any for Class I devices and they don't think the savings will be significant enough to warrant one – for now. In the U.S., Class I devices don't require pre-market authorization; however, manufacturers do have QMS-like requirements (Quality System Regulation/Good Manufacturing Practices). Internationally, this is much akin to ISO 13485 compliance. The process is primarily paper-based, but FDA is required to audit facilities from time-to-time.

Canada has issued a memo allowing re-manufacturing under existing medical device requirements there. Australia hasn't issued a guidance document yet but will allow re-manufacturing based on existing regulations.

In all markets that I am aware of, the reimbursement is the same for re-manufactured and new devices. This is important, especially for EP, because it improves the profitability of these procedures which historically haven't been very profitable because of the time they require and the high cost of devices.

The industry has been around in the US for 20+ years and has been regulated in the U.S. since 2000. Stryker is the dominant player and probably has close to 70% of the market – they acquired a number of companies and the industry is fairly consolidated with only a few major players. Stryker does Class I and Class II products. Sterilmed (acquired by J&J) used to be #2 but has likely fallen to #3. J&J doesn't really support the business and has allowed it to decline. For them, re-manufacturing is being used as a way to fend-off other re-manufacturers. They offer re-manufactured products but then they don't actually provide them. Because the price of the new product is so much higher than the price for the re-manufactured product, the sales representative has no incentive to offer the cheaper product. Sterilmed is now probably #3 and I'd put Medline Renewal at #2 and then Hygia at #4, but they mainly reprocess Class I devices. Covidien (acquired by Medtronic) also offers re-manufactured Nellcor pulse oximeter sensors but this business is pretty small and it will be interesting to see if Medtronic supports it now post merger with Covidien. There are also some other small players such as Renu (a small company in the Northwest) and Northeast Scientific, which has a varicose vein ablation product. There are other small companies that only have a few products but they aren't that significant and are hard to track.

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There used to be one hospital in Utah that tried to meet re-manufacturing standards but never appears to have actually engaged in reprocessing operations because it could not meet FDA requirements. They appear to have purchased a 510k and tried, but they couldn't meet the other requirements of being a medical device manufacturer.

AMDR's membership consists of Stryker, Vanguard (Germany), Medline Renewal, and Hygia. Sterilmed dropped out after J&J acquired them.

EP and surgical products are the most important. To-date, there are no EP ablation catheters reprocessed in the U.S. but a number of companies are working on them and there will be in the future.

J&J's Biosense Webster has worked hard to create obstacles to re-manufacturing. The OEMs like to make small unnecessary design changes to try to force the re-manufacturer to make new regulatory submissions which slows down the competitive effect of reprocessors in the marketplace.

In terms of the FDA process, the key differences vs. an OEM filing are related to cleaning and performance validation. The re-manufacturers have to include cleaning, sterilization, and performance testing validation to the agency on a premarket basis – information that is not required of OEMs on a premarket basis or at all. The re-manufacturer provides slightly different raw materials information. They don't provide information about the raw material suppliers. Instead, they use reverse engineering, among other techniques, to demonstrate they understand the material composition of the device.

Re-manufacturing has been regulated since 2000, so we have 15 years of history. In 2008, the General Accounting Office (GAO) did an evaluation of FDA's study and concluded, as did FDA, that re-manufactured SUDs were as safe and effective as new and noted no increase in adverse events due to reprocessing vs. OEM devices. OEMs will say that reprocessed devices fail more often and will do what I call the "dirty picture show," where they show examples of products that have failed as the results of reprocessing. These examples are never from purchased re-manufactured product from a regulated provider. They are always products that have been reprocessed in a hospital or inside a J&J lab. We completely agree that reprocessing isn't safe if it isn't done in a regulated way but, when done with a 510K-cleared method, it is safe, effective, and results in a device that is equivalent to the OEM device.

What the OEMs don't want to talk about is that there is a growing body of evidence that re-manufactured devices actually fail less frequently. Take a look at the *Loftus* study. Unlike the OEMs, re-manufacturers can't get away with batch testing. They have to test or inspect the functionality of every single unit. This means that quality is not only equivalent but can be even better than the OEM.

Because re-manufactured products are equivalent to the OEM product, informed consent isn't required in the U.S. or any other market.

I'll tell you an interesting story. Boston Scientific/Microvasive used to offer the same biopsy forceps for one price as a re-useable and at another price as an SUD. The product was exactly the same. Everyone knows that many devices can be re-used but the OEM is the one who gets to decide and they are incentivized to designate a product as single use.

Tracking and labeling are important. We don't use GS1 compliant systems yet in the U.S. but every device has a bar code and is tracked. This is an FDA requirement. It helps to track the number of times a device has been used and it also helps the re-manufacturer ensure that there is a closed loop – i.e.,

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that only one company is re-manufacturing the same device. If the re-manufacturer collects a device with another re-manufacturer's bar code, it would be rejected. In terms of labeling, devices are designated as being for "single-use" and the re-manufacturer's name is listed as well as the information about the original device. The label doesn't have to include the number of times the device has been re-used but the re-manufacturer does have to track this in their system.