

Index

A

- Abdominal hernia repair, 144, 205
- Advanced Medical Technology Association (AdvaMed), 31, 110
- American College of Obstetricians and Gynecologists (ACOG), 91, 200, 201
- American Urogynecologic Society (AUGS), 91, 200, 244
- American Urological Association (AUA) guidelines, 245
- AMS Perigee™ System, 205
- Apogee™ mesh delivery system, 287
- Arcus tendineus rectovaginalis (ATRV), 160
- Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC), 26

B

- Ball-burst test, 179–181, 185
- Bladder outlet obstruction (BOO), 249–251
- Bone pain, 274
- Botulinum toxin A (BoNT-A), 226
- Bridging fibrosis, 177

C

- “Cancer Moonshot” program, 97
- Center for Devices and Radiological Health (CDRH), 43, 45, 46, 75–76, 86, 97
- Center for Drug Evaluation and Research (CDER), 75
- Community-based participatory research (CBPR), 140
- Comorbid conditions, 132

- Comparative effectiveness research (CER), 33–34
- Conservative management, 128
- Continuing medical education (CME), 201
- Continuous quality control feedback loop mechanism, 54
- Converging technologies, 14
- Cost of goods sold (COGS), 29
- Current good manufacturing practice (CGMP), 28–31

D

- De novo urgency, 255
- Disk operating system (DOS) computers, 17
- Dissonance reduction consumer behavior model, 110
- Dyspareunia, 220, 221, 225, 259, 260, 293

E

- Ehlers-Danlos syndrome (EDS), 132
- 18 French Foley catheter, 240
- Endoanal ultrasonography (EAUS), 212, 215
- Endopelvic fascia, 165–168
- Endorectal ultrasonography (ERUS), 212, 215
- Endovaginal ultrasound (EVUS) imaging, 212, 213
- Evidence-based medicine, 3, 35, 56

F

- FDA 510(K) process, 1
- Federal Food Drug and Cosmetic Act (FDCA), 76
- Federal Trade Commission (FTC), 75

Female Pelvic Medicine and Reconstructive Surgery (FPMRS)/urogynecology, 129
 Foley catheter, 236, 240
 Food and Drug Administration Modernization Act (FDAMA), 74, 86
 Food, Drug, and Cosmetic Act (FDCA) violations, 49

G

Gastrocnemius muscles (GC), 226
 Gastrointestinal tract, 219, 220
 Genuine stress urinary incontinence (GSUI), 63
 Good Laboratory Practice (GLP), 26
 Groin pain, 220, 221, 223, 258–259
 Gross domestic product (GDP), 22
 Gynecare TVT[®] retropubic (TVT-R) sling procedure, 63
 Gynemesh PS[™], 182, 183

H

Habitual buying behavior, 107
 Hastings Center, 110
 Health technology assessment (HTA), 35
 Heavyweight meshes, 177, 178
 High pressure-low flow pattern, 250
 Hill Ferguson retractor, 241

I

Indirect blindness, 116, 117
 International Conference on Harmonization (ICH), 28
 International Organization for Standardization (ISO), 26
 International Urogynecological Association (IUGA), 129, 237, 265, 266
 Internet protocol (IP) filings, 23
 Investigational device exemption (IDE), 23

K

Kahun Gynaecological Papyrus, 125, 126

L

Levator ani muscles (LAM), 164–167, 226
 Lighter-weight meshes, 178

M

Manufacturer and User Device Experience (MAUDE) database, 6, 64, 86, 199

Marketing

character, 109
 communications model, 105–106
 complex buyer behavior model, 106–107
 consequences, 109
 consumer behavior knowledge, 104
 continuous research and development, 115
 deontological and teleological approaches, 108–109
 dissonance reduction model, 107–108
 ethical breakdowns, 109
 ethical responsibilities, 112
 exchange-based model, 109–111
 field of ethics, 103
 510(k) clearance, 112–114
 implantation of, 104
 informed consent, 111–112
 low involvement model, 107
 manufacturers, 104
 marketers and physicians, 118–119
 marketing mix, 105
 ObTape[®] incontinence, 114
 pharmaceutical and device products, 113
 PMA, 112
 principles, 109
 ProtoGen withdrawal, 114–118
 surgeons, 119–121

Master of Business or Health Administration (MBA/MHA) students, 10

McKinlay's seven-stage model
 complex healthcare settings, 65, 66
 erosion and discreditation, 68–69
 hormonal replacement therapy, 66
 observational reports, 67
 professional and organizational adoption, 67
 public acceptance, 67
 RCTs, 68
 reports, 66–67
 third-party payers, 67

Medical Device Amendments (MDA)

Class I device, 79
 Class II devices, 79
 Class III devices, 79–80
 classification, 77
 comparative efficacy, 79
 Dalkon Shield, 76
 definition, 76

- equivalence creep, 78
- FDCA, 76
- food and drug law, 77
- gold standard, 78
- legislation, 77
- official National Formulary, 76
- PMA, 78
- primary intended purposes, 77
- product approval process, 79
- synthetic meshes, 77
- Medical device innovations, 16–21, 35–52
 - adverse events and recalls
 - causes, 49–51
 - device procode, 46–48
 - radiation-emitting products, 45–47
 - regulatory violations, 49
 - software design failures, 51–52
 - violative product, 43
 - assessment
 - abnormal use, 38
 - cancer treatment, 35
 - cost-effective, 35
 - examples, 41–44
 - failure evaluation, 38
 - feedback loop, 36–37
 - goods and services, 39
 - healthcare operator, 37
 - in-depth investigation, 37
 - “infrastructure” failures, 37
 - knowledge stages, 39–41
 - physical investment, 39
 - robotic technology, 35
 - Shepherd’s global patterns, 37
 - social, medical, and ethical aspects, 35
 - surgical teams, 36
 - vaginal mesh kit, 38
 - CER, 33–34
 - CGMP, 28–31
 - clinical trials, 31
 - clusters, 34
 - disruptive innovations
 - curiosity-driven inventions, 17
 - demanding customers, 17
 - Detroit carmakers, 17
 - DOS computers, 17
 - evidence-based medicine, 21
 - healthcare institutions, 18
 - healthcare markets, 19
 - industry, 19
 - market-driven inventions, 16, 17
 - mature and productive market positions, 17
 - outpatient procedures, 20
 - past medical devices, 20
 - physician performance, 18
 - primary care physicians, 18
 - progress of, 17, 18
 - Toyota Corolla, 17
 - urogynecologists, 20
 - vaginal mesh companies, 19, 20
 - equipment and personnel innovations, 22
 - factors, 14–16
 - local regulatory standards, 54
 - market dynamics, 52–53
 - multinational conglomerates, 21
 - patent process, 21–26
 - portfolio challenge, 31, 32
 - preclinical facilities, 26–28
 - reimbursement challenge, 31, 32
 - supply chain management, 22
 - systematic methods, 54, 55
 - valley of death, 23, 27
- Medical Devices Advisory Committee Meeting, 128
- Mesh complications, 204–207, 211–215, 223, 234–236, 239–242
 - contraction, 216–218
 - extrusion, 218, 219
 - FDA, 234
 - history, 237
 - intraoperative ultrasound, 223–227
 - mesh extrusion, 238, 239
 - mesh perforation
 - bladder, 239–241
 - foreskin, 242
 - rectum, 241
 - transvaginal mesh, 239, 240
 - multicompartmental ultrasonographic techniques, 208–210
 - musculoskeletal, 220–223
 - pelvic floor, 203
 - pelvic organ prolapse, 233
 - physical examination, 237, 238
 - polypropylene mesh, 204
 - POP
 - FDA, 207
 - historical perspective, 204–206
 - types, 206, 207
 - randomized controlled trial, 234
 - transvaginal mesh repairs, 204
 - intraoperative considerations, 235–236

- Mesh complications (*cont.*)
 - postoperative considerations, 236
 - preoperative considerations, 234, 235
 - ultrasonographic imaging
 - endoanal approach, 212, 215
 - EVUS, 212, 213
 - instrumentation, 207, 209
 - perineal/introital approach, 211–212
 - slings, 223
 - transvaginal mesh, 214
 - urinary tract/lower gastrointestinal tract/
 - perforation, 219, 220
 - Mesh contraction, 216, 218
 - Mesh erosion, *see* Mesh extrusion
 - Mesh excision, 254, 255
 - Mesh extrusion, 217–219, 234, 235, 237–239, 287
 - Mesh-free surgery, 132
 - Mesh kits, 76–80
 - CDRH, 75–76
 - clinical trial data, 87
 - complications, 4, 7
 - consumer advertising, 80, 87–88
 - device tracking requirements, 86, 87
 - epidemiology, 10
 - example, 10
 - FDA, 73–75
 - 510(k) clearance route, 80–82
 - hip replacement technologies, 87
 - innovation and ideation process, 4, 7
 - level of training lacking, 6
 - local regulations, 4, 9
 - mandatory tracking provisions, 86
 - manufacturers, 85
 - market with variations, 2, 4
 - marketing status, 83, 92–93
 - MAUDE, 86
 - MDA
 - Class I device, 79
 - Class II device, 79
 - Class III devices, 79, 80
 - classification, 77
 - comparative efficacy, 79
 - Dalkon Shield, 76
 - definition, 76
 - equivalence creep, 78
 - FDCA, 76
 - food and drug law, 77
 - gold standard, 78
 - legislation, 77
 - official National Formulary, 76
 - PMA, 78
 - primary intended purposes, 77
 - product approval process, 79
 - synthetic meshes, 77
 - mean rate, 8
 - medical-legal issues, 73
 - medical profession's response, 90–92
 - medical reviewers, 86
 - medical school education, 4, 8
 - mesh-related pain and surgical procedures, 72
 - patient safety, 4, 6
 - plaintiff's bar, 93–95
 - post-marketing regulations, 84
 - product failure, 9
 - recommendations, 96
 - reporting requirements, 84, 85, 87
 - safety collection system, 88–90
 - state court lawsuits, 95–96
 - Swiss cheese theory, 4, 5
 - transvaginal mesh products, 82–84
 - 21st Century Cures Act, 97–98
 - ultrasound, 8
 - Mesh mechanics, 179–182
 - boundary conditions, 185–186
 - cyclic loading, 185
 - tensile loading, 182–185
 - textile and structural properties
 - ball-burst tests, 180, 181
 - knit pattern and pore geometry, 179
 - load-elongation curve, 179, 180
 - stiffness, 179–182
 - uniaxial tensile test, 179–181
 - Mesh perforation
 - bladder, 239
 - fornix, 242
 - rectum, 241
 - transvaginal mesh, 239, 240
 - Mesh weight, 177
 - Mesh-vaginal tissue, 187
 - Midurethral sling (MUS), *see* Transobturator (TOT) sling
 - Motivated blindness, 117
 - Multi-district litigations (MDLs), 94
- N**
- National Evaluation System for health Technology (NEST), 42
 - National Institutes of Health (NIH), 97
 - Neuroanatomy, 3
 - Nonsurgical treatments, 132
- O**
- Obturator neuropathy, 276, 277
 - Office of Regulatory Affairs (ORA), 45

P

- Pain management, 272, 273
 - anterior rectus muscle trauma, 274
 - biologic grafts, 264
 - bone pain, 274
 - coccygeus muscle, 274
 - fibrosis, 275
 - indications, 264
 - International Urogynecology Association and International Continence Society, 265–267
 - intraoperative and postoperative complications, 265, 269
 - mesh shrinkage-related injury, 275
 - mesh treatment pathway, 265, 268
 - obturator exploration, 265, 269
 - obturator neuropathy, 276, 277
 - pelvic pain
 - autonomic innervation, 272, 273
 - somatic innervation, 273
 - pelvic reconstructive surgery, 264
 - pudendal nerve dissection, 265, 268
 - pudendal neuropathy, 277
 - randomized controlled trials, 264
 - risk, 263
 - somatic nerve injury, 274, 275
 - synthetic mesh, 265, 270, 271
- Patent Cooperation Treaty (PCT), 26
- Patient surveillance postsurgery, 136
- Pelvic floor disorders, 154–169
 - anatomy and prolapse
 - anterior compartment, 154–158
 - apical segment, 154
 - endopelvic fascia, 165–168
 - lateral compartment, 164, 165
 - levator ani muscles, 164, 165
 - perineal membrane, 157, 158
 - posterior compartment and perineal membrane, 159–163
 - pudendal nerve, 169
 - compartments, 145, 146
 - incidence, 143, 144
 - levator ani muscle, 146, 147, 151–153
 - medical specialties, 147, 148
 - midsagittal anatomy, 147, 148
 - PFDR, 200
 - POP and fecal incontinence, 149, 151
 - pubocervical fibromuscularis and rectovaginal fascia, 146
 - retropubic anatomy, 147
 - room analogy, 145
 - suspension bridge, 147, 149, 150
 - synthetic meshes, 144
- Pelvic Floor Disorders Registry (PFDR), 65, 200
- Pelvic floor dysfunction patients, 3
- Pelvic floor muscles, 3, 151
- Pelvic floor myalgias, 220, 224
- Pelvic organ prolapse (POP), 73, 82, 83, 130, 204–207
 - CBPR, 140
 - continual evaluation, 141
 - demographic range and aspects, 126, 127
 - diagnostic clinician practice gap, 126
 - evolution of, 125
 - healthcare practice, 125
 - history of healthcare, 141
 - medical community, 140
 - medical record, 125, 126
 - mesh complications
 - FDA, 207
 - historical perspective, 204–206
 - types, 206, 207
 - mesh procedures, 127–130
 - patient safety, 137, 138
 - pelvic floor ballast postsurgery, 141
 - prevalence, 126
 - QOL, 139
 - regulatory evolution, 134
 - stress incontinence, 61
 - surgical outcomes, 284
 - symptoms, 141
 - technology, 134–137
 - tunnel vision, 130–133
 - urogynecologic mesh, 175
 - workforce, 133–134
- Pelvic organ prolapse quantification (POP-Q), 157, 234
- Pelvic pain, 220, 221, 223
- Pelvic viscera, 272
- Perigee™ system, 287
- Perineal membrane, 162
- Perineal pelvic floor ultrasound (pPFUS), 225
- Pfannenstiel incision, 240
- Polypropylene mesh (PPM), 177, 204, 212, 285
- Pore collapse, 183
- Predicate device drift, 82
- Pre-market approval (PMA) process, 78, 112
- Prolapse surgery
 - FDA medical device regulation, 198, 199
 - history, 195–197
 - implantation training, 196, 199
 - PFDR, 200
 - training and guidelines, 200, 201
- Prolift, 206
- ProteGen sling, 195, 205
- ProtoGen technology, 113
- Public health notifications (PHNs), 173

Puboanal, 164
 Pubocervical fibromuscularis, 145–147, 152, 155–157
 Puboperinealis fibers, 162
 Puborectalis, 164
 Pubovaginalis, 164
 Pudendal nerve, 169
 Pudendal neuralgia, 224
 Pudendal neuropathy, 277

Q

Q-tip, 225
 Quality of life (QOL), 139, 287
 Quality System Regulation (QSR), 28, 49

R

Randomized Controlled Trials (RCTs), 66, 68, 234, 264, 286, 288, 289
 Rectal injury, 3
 Rectovaginal fibromuscularis (RVF), 160, 161, 165, 167
 Rectus fascia, 240
 Research and development (R&D) process
 preclinical facilities, 26–28
 valley of death, 23, 27
 Restorelle™, 182
Riegel v. Medtronic, 95
 RVF, *see* Rectovaginal fibromuscularis

S

Sacrocolpopexy, 204
 Safe Medical Devices Act of 1990 (SMDA), 86
 Serious adverse events (SAEs), 77
 Single-incision kits, 290–292
 Single-incision slings (SIS), 282–284
 Slippery slope effect, 117
 Small- and medium-sized companies (SMEs), 29, 30
 Somatic nerve injury, 274, 275
 Stress urinary incontinence (SUI), 73, 173, 195, 205, 243, 244
 Suprapubic pain, 221
 Surgical mesh devices, 195
 Synthetic mesh, 71, 73, 77, 144, 158, 177, 179–182, 189, 200, 233, 256, 281, 286
 augmentation, 234
 classification, 265, 267, 270
 pelvic organ prolapse surgery, 264
 shrinkage, 217

 transvaginal placement, 281
 types, 206–207
 Synthetic polypropylene mesh, 195

T

Tension-free vaginal tape (TVT) system, 1, 2, 20, 281, 282

Textile properties

 filament type, 176
 knit pattern, 176, 177
 mesh weight, 177, 178
 pore size and porosity, 177
 3D 360 endoanal imaging, 209, 210
 3D printer technology, 32
 Transobturator (TOT) sling, 245–258
 anatomy, 246, 247
 AUA guidelines, 245
 complications
 classification, 246
 exposure/extrusion, 257
 hemorrhage, 247, 248
 physical examination, 256
 rate, 245
 recurrent UTI, 257–258
 ureteral injury, 249
 urethral erosion rate, 256
 urinary tract perforation, 248, 249
 voiding dysfunction, 249–251
 wound infections, 258

 contraindications, 245
 de novo urgency, 255
 dyspareunia, 259, 260
 groin pain, 258, 259
 indication, 245
 MUS placement, 244
 retropubic space, 245
 SUI, 243, 244
 urinary retention and obstruction
 incidence, 251
 mesh excision, 254, 255
 MUS incision, 252, 253
 surgical intervention, 251
 temporary urethral, 251
 transvaginal urethrolysis, 254, 255
 Transvaginal mesh (TVM), 200, 204, 214, 292–297
 mesh complications
 intraoperative considerations, 235, 236
 postoperative considerations, 236
 preoperative considerations, 234, 235
 nontrocar-assisted procedures, 284
 outcomes of mesh procedures, 128
 prolapse

- anatomic outcome, 294
 - complications, 293, 294
 - erosion, 292, 293
 - subjective outcome, 294–297
 - single-incision kits, 290–292
 - surgical complications, 129
 - sutured-in hand-cut, 285, 286
 - trocar-assisted procedures, 284
 - trocar-based kits, 286–289
 - Transvaginal urethrolysis, 254, 255
 - Trial of Midurethral Slings (TOMUS), 245–246
 - Trocar-based system, 235
 - 2D endovaginal/introital anterior compartment imaging, 209
 - 2D endovaginal posterior compartment imaging, 209
- U**
- UltraPro™, 182
 - Uniaxial tensile test, 179–181, 185
 - Unique device identifiers (UDI), 57
 - Ureteral injury, 249
 - Urinary incontinence (UI), 20, 56, 143, 219, 233, 256, 282–284
 - Urinary tract infections (UTI), 132, 133, 257, 258
 - Urinary tract perforation, 248, 249
 - Urogenital diaphragm, 157–159
 - Urogynecologic mesh, 174–176, 186–188
 - future aspects, 189, 190
 - host response, 176, 178
 - animal and human studies, 187–188
 - inflammatory response, 186
 - mesh mechanics (*see* Mesh mechanics)
 - mesh textile properties (*see* Textile properties)
 - modification, 188
 - pelvic floor
 - biological environment, 174
 - mechanical environment, 175
 - vaginal vs. abdominal host response, 175, 176
 - transvaginal mesh, 173
 - Urogynecology/female pelvic medicine and reconstructive surgery (FPMRS), 19
- V**
- Vaginal mesh, 62–65
 - hype cycle
 - application, 62
 - disillusionment, 64
 - peak of inflated expectations, 63–64
 - phases, 62
 - productivity, 65
 - slope of enlightenment, 64–65
 - technology trigger, 62–63
 - McKinlay's seven-stage model
 - complex healthcare settings, 65, 66
 - erosion and discreditation, 68–69
 - hormonal replacement therapy, 66
 - observational reports, 67
 - professional and organizational adoption, 67
 - public acceptance, 67
 - RCTs, 68
 - reports, 66–67
 - third-party payers, 67
 - Vaginal shortening, 221
 - Vaginal tightness, 221
 - Vesicovaginal fistula (VVF), 239
 - Voiding dysfunction, 249–251
- W**
- Wound infections, 258
- X**
- X12, 57
- Y**
- Years lived with disability (YLD) questionnaires, 44