

CRITICAL LIMB ISCHEMIA VOLUME I INDEX OF TABLES

Table 1: Occlusion Types, Duration and Characteristics	12
Table 2: Critical Limb Ischemia Risk Factors	13
Table 3: Critical Limb Ischemia Fontaine and Rutherford Classification Systems	14
Table 4: BASIL Trial 30-Day Mortality and Morbidity	20
Table 5: PREVENT III 30-Day Mortality and Morbidity	21
Table 6: Critical Limb Ischemia Cause of Death	24
Table 7: Critical Limb Ischemia Comorbid Conditions Present in Patients Undergoing Revascularization	25
Table 8: Dialysis Outcomes and Practice Patterns Study (DOPPS) Prevalence of PAD and CLI in ESRD Patients	38
Table 9: Incidence of New PAD In Medicare Patient Sample According to Presence of Diabetes and CKD	41
Table 10: Severity of Baseline Critical Limb Ischemia By Level of Renal Dysfunction	42
Table 11: One-Year Mortality by Renal Function and Severity of Limb Ischemia at Diagnosis	43
Table 12: Summary of CLI Incidence Research And Incidence Calculations for the U.S. 2006	48
Table 13: OXVASC CLI Incidence per Million Population	52
Table 14: 2006 U.S. CLI Prevalence Calculated from Incidence Assuming 15% or 20% Annual Mortality	53
Table 15: Summary of CLI Prevalence Research and 2006 Prevalence In the U.S.	54
Table 16: HUNT Study CLI Prevalence by Age and Sex	58
Table 17: New South Wales Study CLI Prevalence by Age and Sex	60

Table 18: PAD Prevalence in Diabetes	63
Table 19: Cardiovascular Health Study Prevalence of Clinical and Subclinical PAD In Males and Females Age ≥ 65 Categorized by Glucose Status	64
Table 20: The Hoorn Study Prevalence of PAD in Individuals Age 50-74 Categorized by Glucose Status	65
Table 21: The Hoorn Study Prevalence of PAD Categorized by Age Group and Glucose Status	65
Table 22: Percentage of PAD by Age Group in Newly Diagnosed Type 2 Diabetics	66
Table 23: East Dorset PAD Prevalence by Age and Sex in Type 2 Diabetics and Nondiabetics	68
Table 24: NHANES II Percentage of Diabetics and Nondiabetics with PAD	69
Table 25: 2000-2020 U.S. Critical Limb Ischemia in Population Age ≥ 45	70
Table 26: U.S. Population Age ≥ 65 Glucose Status by Sex NHANES 1999-2002	71
Table 27: U.S. Population Age ≥ 65 PAD Prevalence by Sex and Glucose Status	72
Table 28: U.S. Population Age ≥ 65 CLI Prevalence in PAD By Glucose Status	72
Table 29: U.S. Population Age 45- 64 By Glucose Status NHANES 1999-2002	73
Table 30: U.S. Population Age 45-64 PAD Prevalence by Glucose Status	73
Table 31: U.S. Population Age 45-64 CLI Prevalence in PAD By Glucose Status	74
Table 32: United States 2005-2020 Percentage of Diagnosed Diabetes For Selected Years and Age Groups	74
Table 33: U.S. 2005-2020 Comparison of CLI Estimates Based on Constant or Increasing Prevalence of Diagnosed Diabetes	75

Table 34: 2006 U.S. CLI Market in Procedures and Dollars Current Endovascular Market and Potential Endovascular Market	77
Table 35: U.S. 2006 Critical Limb Ischemia Appropriate Treatment Pathway for Potential Market Estimates	78
Table 36: 2006-2020 U.S. Market Potential for Antihypertensive Pharmaceuticals to Treat Critical Limb Ischemia Patients	82
Table 37: 2006-2020 U.S. Market Potential for Antilipid Pharmaceuticals to Treat Critical Limb Ischemia Patients	83
Table 38: 2006-2020 U.S. Market Potential for Antiplatelet Pharmaceuticals to Treat Critical Limb Ischemia Patients	83
Table 39: United States 2005-2020 Estimated Number of People with PAD Comparison of Two Methods	86

INDEX OF FIGURES

Figure 1: Consequences of Critical Limb Ischemia	17
Figure 2: One-Year Amputation Rate Inversely Associated with ABI in CLI Patients Unsuitable for Revascularization	18
Figure 3: Five-Year All-Cause Mortality CLI, ALI and Selected Diseases	22
Figure 4: Four-Year Event-Free Survival IC, CLI and ALI	23
Figure 5: Ten-Year Mortality for PAD by Disease Severity Compared to Survivors of First Heart Attack	24
Figure 6: 2005 U.S. Adult Population ≥ 18 Percentage of Diabetes and Prediabetes	27
Figure 7: 1970s to 2006 Percentage of Diagnosed Diabetes Age 65 and Over	28
Figure 8: Diabetes as a Percentage of the U.S. Adult Population and Diabetes as a Percent of the U.S. CLI Population	33
Figure 9: 1978-2030 Number of Actual and Projected U.S. ESRD Patients	36
Figure 10: Prevalence of PAD at Baseline In a Medicare Patient Sample According to Presence of Diabetes and Chronic Kidney Disease	40
Figure 11: One-Year Mortality in Patients with CLI Only or ESRD Only or CLI and Severe Kidney Disease by Severity of Ischemia	43
Figure 12: One-Year Amputation-Free Survival After Surgical Revascularization In Dialysis Patients and Patients with Normal Kidney Function	45
Figure 13: Five-Year Survival in ESRD Patients Categorized by Comorbidity and Risk Factors	46
Figure 14: 2006 Market Potential Based on Varying Percentage of Treatment with New Endovascular Technologies	80
Figure 15: 2006 Market Potential Based on Increased Percentage of Treatment with DES/New Stents	81