To estimate the **Potential Peak Sales** for the Sonalleve MR-HIFU system for the treatment of osteoid osteoma in the extremities in the US, EU5 (France, Germany, Italy, Spain, UK), China, and Japan, as well as the **$ value of a 1% share of treated patients** in these geographies, we need to follow a structured approach. Since specific data on the exact number of treated patients or pricing may not be publicly available, I will make reasonable assumptions based on epidemiology, market dynamics, and treatment costs. I will also outline the steps and assumptions clearly for transparency.

Indication Overview: Osteoid Osteoma

- **Osteoid osteoma** is a benign bone tumor, most commonly affecting children and young adults, often in the extremities. It accounts for approximately 10-12% of benign bone tumors.

- The standard treatment is often surgical intervention or radiofrequency ablation (RFA), but non-invasive options like MR-HIFU (Magnetic Resonance-guided High-Intensity Focused Ultrasound) are emerging as alternatives due to reduced recovery time and lower risk.

- The Sonalleve MR-HIFU system by Profound Medical Inc. was approved by the FDA for this indication, offering a non-invasive treatment option.

Step 1: Estimate the Target Patient Population

We need to estimate the number of patients with osteoid osteoma who are eligible for treatment in each geography. Since osteoid osteoma is rare, I will use incidence rates and population data to estimate the annual number of cases.

- **Incidence Rate**: Osteoid osteoma incidence is estimated at approximately 0.1 to 0.3 per 100,000 people per year (based on literature and rare disease databases).

- **Population Data (2023 estimates)**:

- US: ~330 million

- EU5 (France, Germany, Italy, Spain, UK): ~320 million

- China: ~1,400 million

- Japan: ~125 million

- **Annual Incident Cases (using midpoint incidence of 0.2 per 100,000)**:

- US: 330M * 0.2/100,000 = ~660 cases/year

- EU5: 320M * 0.2/100,000 = ~640 cases/year

- China: 1,400M * 0.2/100,000 = ~2,800 cases/year

- Japan: 125M * 0.2/100,000 = ~250 cases/year

- **Total Annual Incident Cases**: 660 + 640 + 2,800 + 250 = **4,350 cases/year**

Note: This assumes all cases are diagnosed and eligible for treatment, which may not be the case. Some cases may be asymptomatic or untreated, so we might adjust downward by ~20% for treatable cases:

- **Treatable Cases per Year**: 4,350 * 0.8 = **3,480 cases/year**

Breakdown of treatable cases:

- US: 660 * 0.8 = ~530 cases

- EU5: 640 * 0.8 = ~510 cases

- China: 2,800 * 0.8 = ~2,240 cases

- Japan: 250 * 0.8 = ~200 cases

Step 2: Market Share Assumption (20% to 30%)

The question assumes a 20% to 30% share of treated patients for the Sonalleve MR-HIFU system. This reflects the proportion of eligible patients who would adopt this treatment over alternatives like surgery or RFA.

- **Midpoint Share (25%) for Peak Sales Calculation**:

- US: 530 * 0.25 = ~133 patients/year

- EU5: 510 * 0.25 = ~128 patients/year

- China: 2,240 * 0.25 = ~560 patients/year

- Japan: 200 * 0.25 = ~50 patients/year

- **Total Patients Treated at Peak (25% share)**: 133 + 128 + 560 + 50 = **871 patients/year**

- **Range for Sensitivity (20% to 30%)**:

- 20% share: 3,480 * 0.2 = ~696 patients/year

- 30% share: 3,480 * 0.3 = ~1,044 patients/year

Step 3: Treatment Cost per Patient

The cost of MR-HIFU treatment varies by region due to differences in healthcare systems, reimbursement, and pricing. Since exact pricing for Sonalleve MR-HIFU is not publicly available, I will estimate based on comparable non-invasive treatments (e.g., RFA or other HIFU systems) and market reports. Costs typically include the procedure, equipment usage, and hospital fees.

- **Estimated Cost per Treatment (Assumptions)**:

- US: $15,000 (higher due to private healthcare system)

- EU5: $10,000 (average across public/private systems)

- China: $5,000 (lower due to cost controls and market dynamics)

- Japan: $12,000 (higher due to advanced healthcare system but cost controls)

These are rough estimates and could vary based on reimbursement policies, hospital contracts, and market penetration strategies by Profound Medical Inc.

Step 4: Calculate Potential Peak Sales

Peak sales are calculated by multiplying the number of treated patients (at 25% share) by the cost per treatment in each region.

- **Peak Sales at 25% Share**:

- US: 133 patients * $15,000 = **$1.995 million**

- EU5: 128 patients * $10,000 = **$1.28 million**

- China: 560 patients * $5,000 = **$2.8 million**

- Japan: 50 patients * $12,000 = **$0.6 million**

- **Total Peak Sales (25% share)**: $1.995M + $1.28M + $2.8M + $0.6M = **$6.675 million/year**

- **Range for Sensitivity (20% to 30% share)**:

- 20% share:

- US: 106 * $15,000 = $1.59M

- EU5: 102 * $10,000 = $1.02M

- China: 448 * $5,000 = $2.24M

- Japan: 40 * $12,000 = $0.48M

- **Total (20%)**: $5.33 million/year

- 30% share:

- US: 159 * $15,000 = $2.385M

- EU5: 153 * $10,000 = $1.53M

- China: 672 * $5,000 = $3.36M

- Japan: 60 * $12,000 = $0.72M

- **Total (30%)**: $7.995 million/year

Thus, **Potential Peak Sales Range**: **$5.33 million to $7.995 million per year**, with a midpoint of approximately **$6.675 million/year**.

Step 5: Calculate $ Value of 1% Share of Treated Patients

A 1% share of treated patients corresponds to 1% of the total treatable cases (3,480 patients/year) = **34.8 patients/year**.

- **Breakdown by Region (1% share)**:

- US: 530 * 0.01 = 5.3 patients

- EU5: 510 * 0.01 = 5.1 patients

- China: 2,240 * 0.01 = 22.4 patients

- Japan: 200 * 0.01 = 2.0 patients

- **Revenue for 1% Share**:

- US: 5.3 * $15,000 = **$79,500**

- EU5: 5.1 * $10,000 = **$51,000**

- China: 22.4 * $5,000 = **$112,000**

- Japan: 2.0 * $12,000 = **$24,000**

- **Total $ Value of 1% Share**: $79,500 + $51,000 + $112,000 + $24,000 = **$266,500/year**

Final Answer

1. **Potential Peak Sales for Sonalleve MR-HIFU System** (20% to 30% share of treated patients):

- Range: **$5.33 million to $7.995 million per year**

- Midpoint (25% share): **$6.675 million per year**

2. **$ Value of 1% Share of Treated Patients**:

- Total across US, EU5, China, and Japan: **$266,500 per year**

Caveats and Assumptions

- **Epidemiology**: Incidence rates are estimates and may vary. Diagnosis rates and treatment-seeking behavior could differ by region.

- **Pricing**: Treatment costs are assumed based on comparable therapies and may not reflect actual pricing or reimbursement levels for Sonalleve MR-HIFU.

- **Market Share**: The 20-30% share assumes moderate adoption, but competition from RFA and surgery, as well as regulatory/reimbursement hurdles, could impact this.

- **Market Access**: Assumes the device is approved and accessible in all mentioned regions, which may not yet be the case for China or others beyond the US.

If you have access to more precise data on incidence, pricing, or market penetration, these estimates can be refined accordingly.