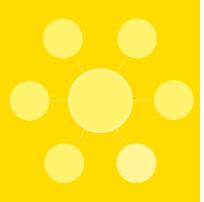


# **Patient Access**

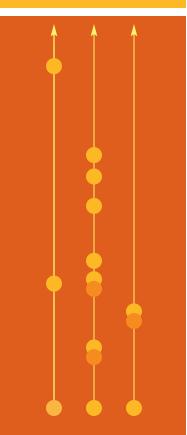




#### Overview

In 2022, with nearly 100,000 patients treated, the field exceeded 500,000 cumulative patient treatments. Pancreatic cancer is the leading cancer indication for focused ultrasound treatments in 2022. Urological and women's health are the two body systems that have the most treatment sites with more than 500 each. This is not surprising as prostate disease and uterine fibroids were some of the earliest indications to have regulatory approval around the world.





#### **VII.** Patient Access

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- VII. 3 Treatment Highlights

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# Treatment Highlights



# A leading indication



**Pancreatic cancer treatments** 

# Body systems with the most treatment sites





Women's health 9 indications

#### Commercial Treatment Sites by Region

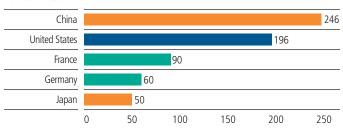


Number of Sites **Commercial Treatment Sites** 219 **North America** 25% Annual Growth from 2013-2022 29 Europe 4% Annual Growth from 2013–2022 Asia 12% Annual Growth from 2013-2022 South America 4% Annual Growth from 2013–2022 Oceania 19% Annual Growth from 2013-2022

#### **Top Countries for Treatment**

**Top Countries** 

Number of sites



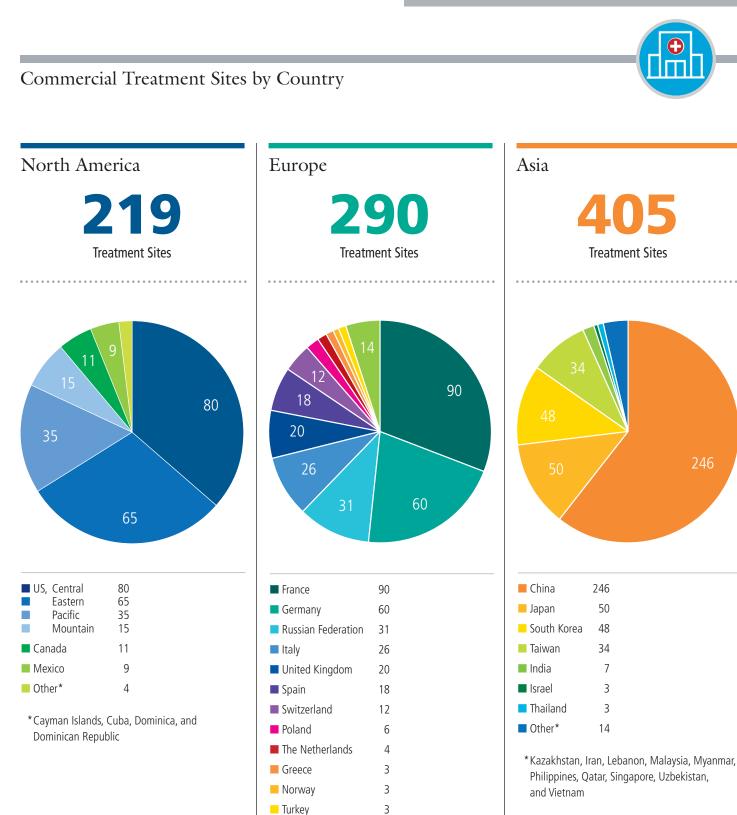
#### Top Countries with Commercial Treatment Growth

Sites added, cumulative 2017 to 2022

United States							149 (27%)		
China		112 (11%)							
South Korea		27 (	15%)						
France		19 (4%)							
Taiwan		15 (10%	b)						
	0	25	50	75	100	125	150		

In 2022 there were 32 new commercial treatment sites of which 28 were in the United States. While China remains the top country in the world for commercial treatment with 246 sites, the United States is quickly closing the gap with 196 sites.

Africa 15% Annual Growth from 2013–2022



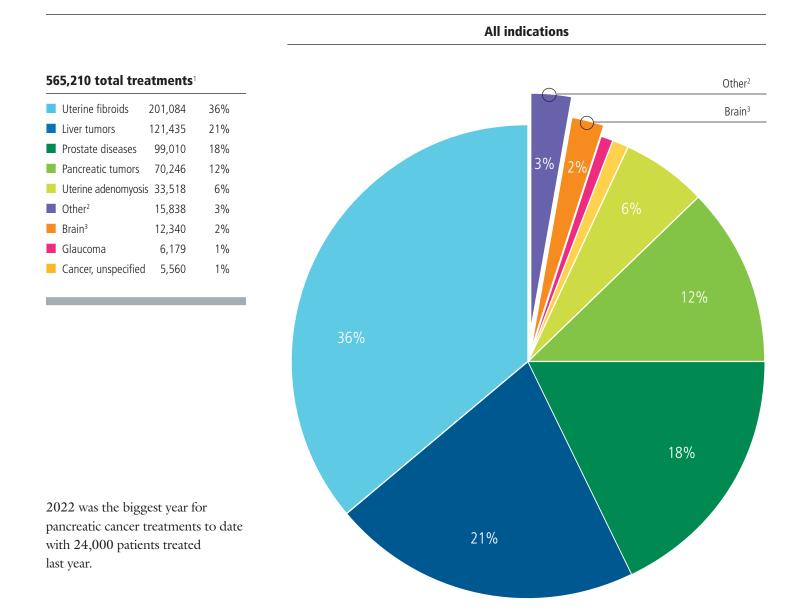
Other\*

14

\* Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland, Georgia, Latvia, Monaco,

Portugal, Romania, and Ukraine

#### Patient Treatments by Indication-Cumulative

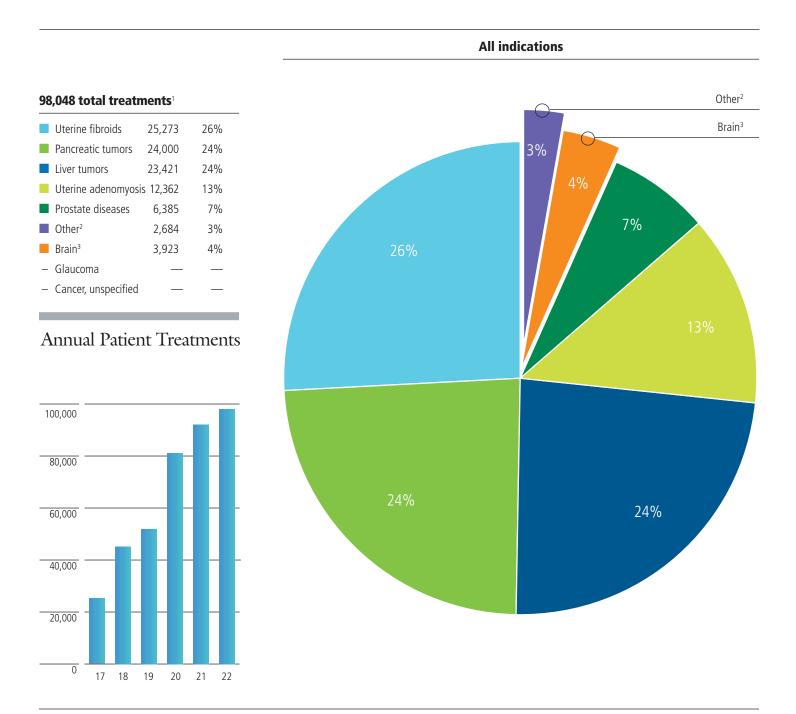


2 For an expanded list of these indications, please refer to Cumulative Other Treatments by Indication, on p. VII.12.

3 For an expanded list of these indications, please refer to Cumulative Brain Treatments by Indication, on p. VII.10.

<sup>1</sup> The number of patient treatments reported is lower than the actual number of procedures because of incomplete reporting from manufacturers and treatment sites. Companies reporting patient treatment values this year were: Arrayus, Cardiawave, CarThera, EDAP TMS, EpiSonica, FUSMobile, HistoSonics, Insightec, NaviFUS, Profound Medical, Shanghai A&S, Shenzhen PRO-HITU Medical, Sonablate, Theraclion, TOOsonix, and VeinSound.

#### Patient Treatments by Indication-2022

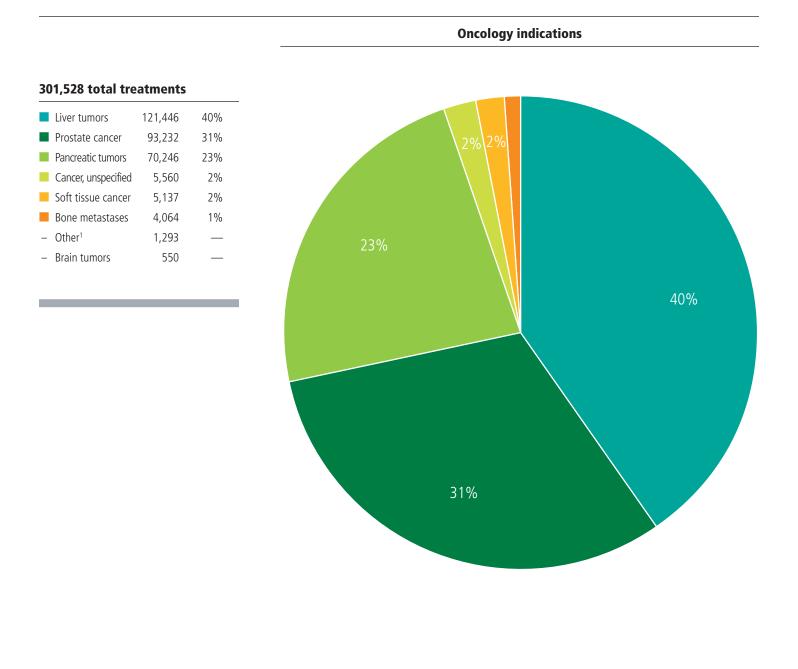


1 The number of patient treatments reported is lower than the actual number of procedures because of incomplete reporting from manufacturers and treatment sites. Companies reporting patient treatment values this year were: Arrayus, Cardiawave, CarThera, EDAP TMS, EpiSonica, FUSMobile, HistoSonics, Insightec, NaviFUS, Profound Medical, Shanghai A&S, Shenzhen PRO-HITU Medical, Sonablate, Theraclion, TOOsonix, and VeinSound.

2 For an expanded list of these indications, please refer to Other Treatments by Indication, on p. VII.13.

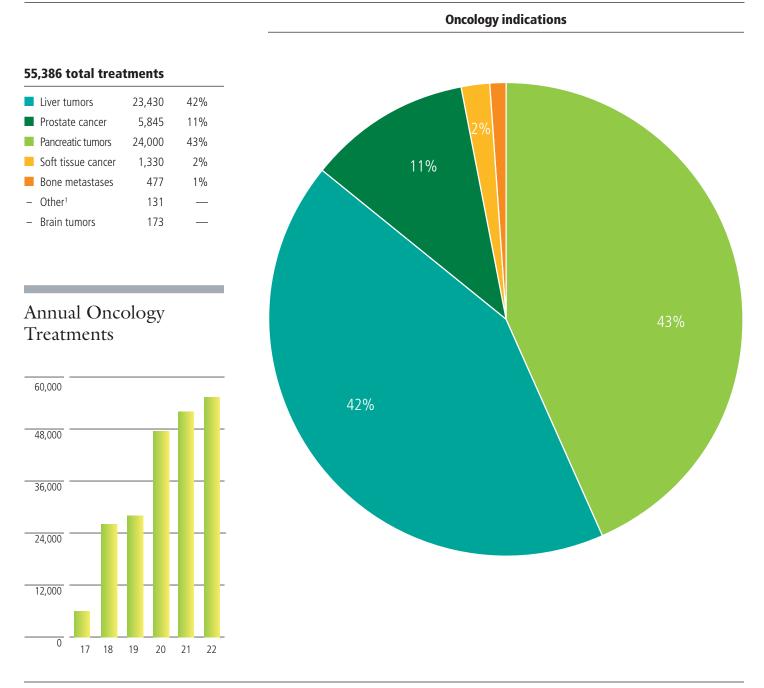
3 For an expanded list of these indications, please refer to Brain Treatments by Indication, on p. VII.11.

#### Oncology Treatments by Indication-Cumulative



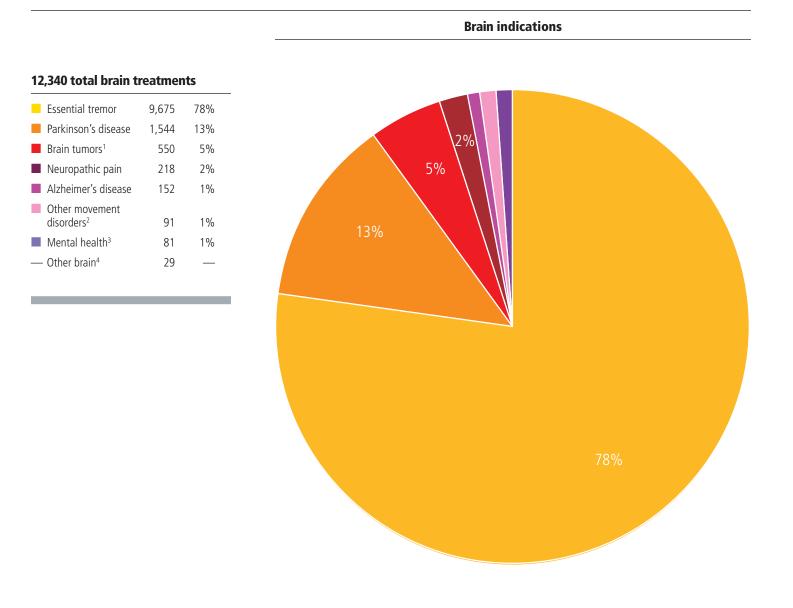
1 Includes, in descending order of patient treatments: breast tumors, malignant; endometrial tumors; neurofibromatosis; kidney tumors; bone cancer; basal cell carcinoma; abdominal paraganglioma; hemangioma; abdominal tumors; granular cell tumors of the gluteals; Kaposi's sarcoma; cervical tumors; sacral chordoma; schwannoma; and spleen tumors

### Oncology Treatments by Indication-2022



1 Includes, in descending order of patient treatments: endometrial tumors; glioblastoma; brain tumors, general; glioblastoma multiforme; diffuse intrinsic pontine glioma (DIPG); basal cell carcinoma; and bone cancer

#### Brain Treatments by Indication—Cumulative



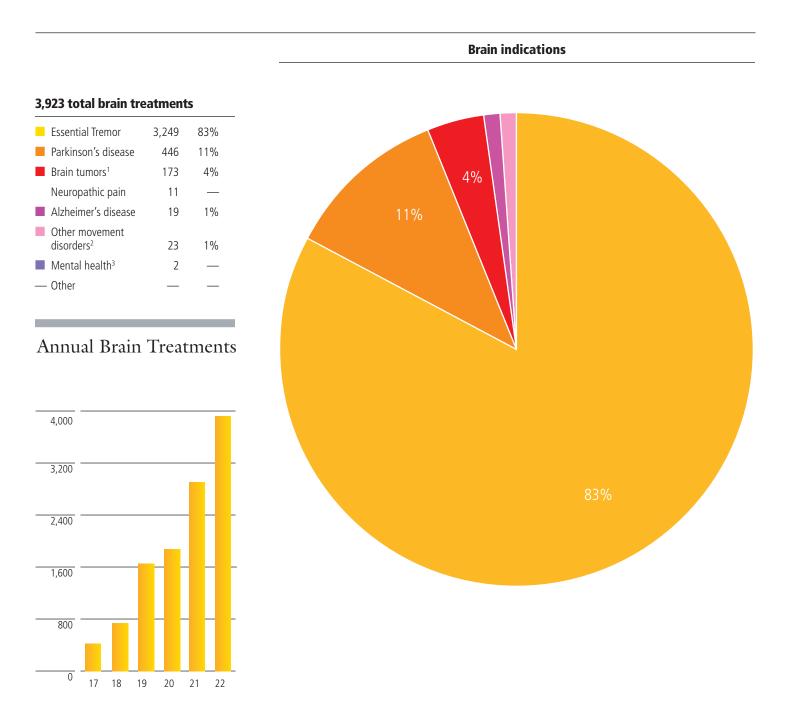
<sup>1</sup> Includes, in descending order of patient treatments: glioblastoma; brain tumors, general; astrocytoma; pontine glioma; and ganglioglioma

<sup>2</sup> Includes, in descending order of patient treatments: epilepsy; dystonia; and dystonia, hand

<sup>3</sup> Includes, in descending order of patient treatments: depression, obsessive compulsive disorder (ocd), and anxiety

<sup>4</sup> Includes, in descending order of patient treatments: traumatic brain injury, and blood-brain barrier opening (safety / feasibility)

#### Brain Treatments by Indication-2022

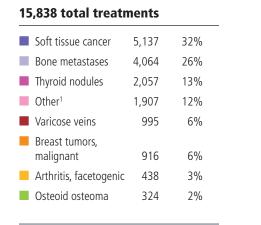


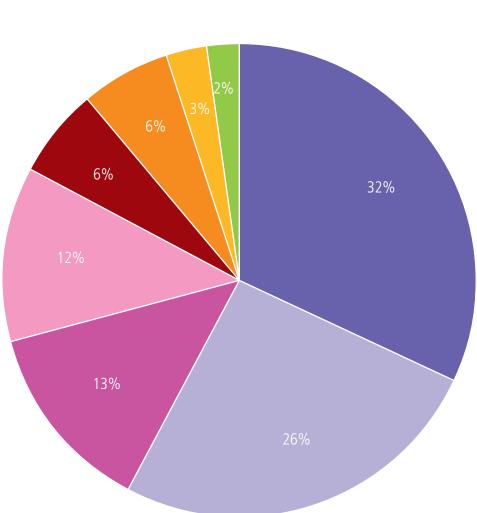
1 Includes, in descending order of patient treatments: glioblastoma and brain tumors, general

2 Includes, in descending order of patient treatments: dystonia, hand; epilepsy; and dystonia

3 Includes, in descending order of patient treatments: obsessive compulsive disorder (OCD)

#### Other Treatments by Indication-Cumulative

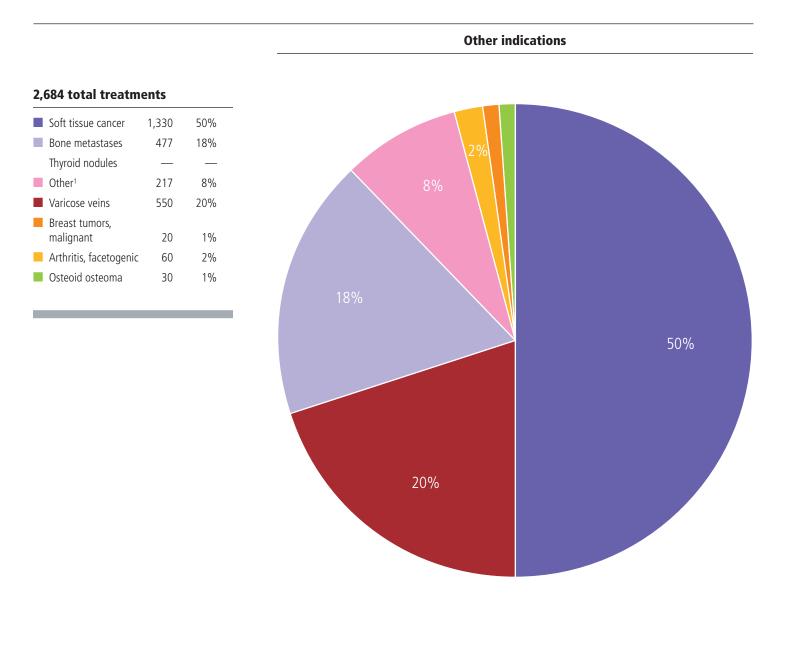




Other indications

<sup>1</sup> Includes, in descending order of patient treatments: breast tumors, benign; endometrial tumors; desmoid tumors; endometriosis; hypertension; heart valve calcifications; hyperparathyroidism; actinic keratosis; arthritis; dermatology research; tattoo removal; neurofibromatosis; bone tumors, benign; kidney tumors; bone cancer; basal cell carcinoma; seborrheic keratosis; vascular malformations and angiomas; painful amputation neuromas; abdominal paraganglioma; hemangioma; peripheral artery disease; Verruca vulgaris; abdominal tumors; amyotrophic lateral sclerosis; arteriovenous malformations; granular cell tumors of the gluteals; Kaposi's sarcoma; cervical tumors; sacral chordoma; schwannoma; soft tissue tumors, benign; and spleen tumors

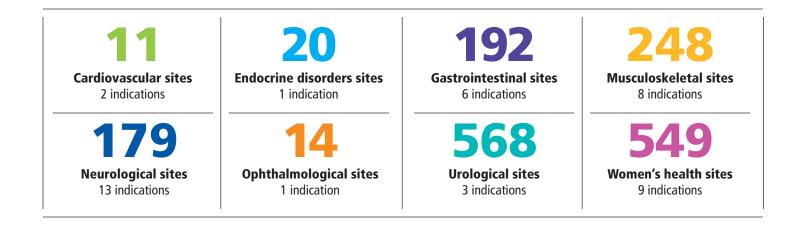
### Other Treatments by Indication-2022



1 Includes, in descending order of patient treatments: endometrial tumors, desmoid tumors, endometriosis, neurofibromatosis, heart valve calcifications, basal cell carcinoma, and Kaposi's sarcoma

Commercial Treatment Sites by Indication and Body System\*





#### Growth of Commercial Treatment Sites



The area of largest growth in 2022 was neurological sites, with 23 additional sites.

#### **Commercial treatment additional content**

For more information about specific commercial treatment sites and indications, please visit:

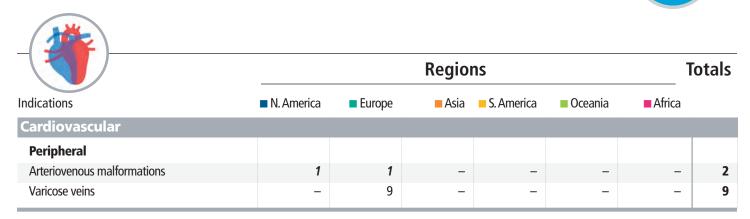
#### www.fusfoundation.org/the-technology/treatment-sites

Use the "search by disease" dropdown menu and/or location.

\*Indications being performed off label in a region are shown in bold italic. A site may perform treatments on more than one indication within the same body system. Because of this, the total number of sites within a body system in the table may not equal the values provided in the summary at the top.

For more information about specific commercial treatment sites and indications, please visit: www.fusfoundation.org/the-technology/treatment-sites. Use the "search by disease" dropdown menu and/or location.

# Commercial Treatment Sites by Indication and Region\*



-	Regions						Totals
Indications	N. America	Europe	Asia	S. America	Oceania	Africa	
Endocrine disorders							
Thyroid nodules	_	13	7	_	_	_	20

<sup>\*</sup>Indications being performed off label in a region are shown in bold italic. A site may perform treatments on more than one indication within the same body system. Because of this, the total number of sites within a body system in the table may not equal the values provided in the summary at the top.

For more information about specific commercial treatment sites and indications, please visit: www.fusfoundation.org/the-technology/treatment-sites. Use the "search by disease" dropdown menu and/or location.

## Commercial Treatment Sites by Indication and Region\* continued

-(~)			Regio	ns			Totals
Indications	N. America	Europe	Asia	S. America	Oceania	Africa	
Gastrointestinal							
Gastric tumors	_	1	_	_	_	_	1
Liver metastases	-	-	2	_	_	1	3
Liver tumors	2	8	126	_	_	1	137
Pancreatic tumors	_	-	41	-	_	-	41
Pancreatic tumors, benign	_	-	1	-	_	_	1
Pancreatic tumors, malignant	1	3	4	-	_	1	9

	Regions								
Indications	N. America	Europe	Asia	S. America	Oceania	Africa			
Musculoskeletal									
Arthritis, facetogenic	1	1	1	_	1	-	4		
Bone cancer	3	2	2	_	-	1	8		
Bone metastases	6	14	5	-	1	1	27		
Bone tumors, benign	-	1	-	_	-	-	1		
Desmoid tumors	4	5	-	_	1	1	11		
Osteoid osteoma	5	11	85	_	1	1	103		
Soft tissue cancer	1	1	-	-	-	-	2		
Soft tissue tumors, benign	1	5	85	_	-	_	92		

For more information about specific commercial treatment sites and indications, please visit: www.fusfoundation.org/the-technology/treatment-sites. Use the "search by disease" dropdown menu and/or location.

<sup>\*</sup>Indications being performed off label in a region are shown in bold italic. A site may perform treatments on more than one indication within the same body system. Because of this, the total number of sites within a body system in the table may not equal the values provided in the summary at the top.

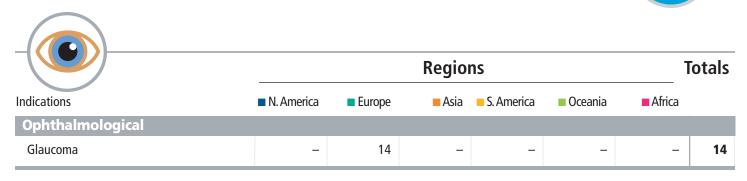
### Commercial Treatment Sites by Indication and Region\* continued

C. C	Regions								
dications	N. America	Europe Asia		S. America	Oceania	Africa			
Neurological									
Movement disorder									
Dystonia	-	1	-	-	-	-	1		
Dystonia, hand	-	_	1	_	-	-	1		
Epilepsy	-	1	1	-	-	-	2		
Essential tremor	51	25	23	1	2	-	102		
Parkinson's disease, dyskinesia	2	3	1	-	-	-	6		
Parkinson's disease, tremor	35	10	10	1	1	-	57		
Neurodegenerative									
Alzheimer's disease	-	-	1	-	-	-	1		
Pain									
Neuropathic pain	_	2	_	_	1	-	3		
Neuropathy	-	1	-	_	-	-	1		
Trigeminal neuralgia	-	1	-	_	-	-	1		
Psychiatric									
Depression	-	-	1	_	-	-	1		
Obsessive-compulsive disorder	1	_	1	_	_	_	2		

<sup>\*</sup>Indications being performed off label in a region are shown in bold italic. A site may perform treatments on more than one indication within the same body system. Because of this, the total number of sites within a body system in the table may not equal the values provided in the summary at the top.

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#### Commercial Treatment Sites by Indication and Region\* continued



-	Regions						
Indications	N. America	Europe	Asia	S. America	Oceania	Africa	
Urological							
Benign prostatic hyperplasia	14	6	25	_	_	-	45
Kidney tumors	1	4	85	-	_	1	91
Prostate cancer	171	210	41	6	1	3	432

<sup>\*</sup>Indications being performed off label in a region are shown in bold italic. A site may perform treatments on more than one indication within the same body system. Because of this, the total number of sites within a body system in the table may not equal the values provided in the summary at the top.

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		Regions								
ndications	N. America	Europe	Asia	S. America	Oceania	Africa				
Women's health										
Breast tumors, benign	_	10	3	_	_	_	13			
Breast tumors, malignant	1	6	89	_	-	-	96			
Cervicitis	_	1	-	_	-	-	1			
Endometrial tumors	_	_	1	_	_	-	1			
Endometriosis	_	2	_	_	-	-	2			
Lichen sclerosis	_	_	1	_	_	-	1			
Urinary incontinence, stress	_	1	-	_	_	-	1			
Uterine adenomyosis	3	7	101	_	2	2	115			
Uterine fibroids	11	32	270	_	2	4	319			

Commercial Treatment Sites by Indication and Region\* continued

\*Indications being performed off label in a region are shown in bold italic. A site may perform treatments on more than one indication within the same body system. Because of this, the total number of sites within a body system in the table may not equal the values provided in the summary at the top.

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