



Building Designing a Surgical Robotics Company To Succeed

DWIGHT MEGLAN

Winter 2022

Why me for this subject?

- Left Mayo tenure track 30 years ago to stay an active engineer
- Worked on
 - Surgical simulators since 1994
 - Surgical robots since 2000
- Worked/working on 11 commercial surgical robots
 - EndoVia (NOTES) 2000
 - Hansen (Catheter) 2003
 - Stereotaxis (EP) 2005
 - HeartLander (Cardiac) 2008
 - Medtronic (Abdominal) 2013
 - Elements Endoscopy (Colonoscopy) 2018
 - JNJ (Abdominal) 2019
 - 2 startups 2021
 - 2 startups 2022
- Part of many surgical robotics company investment & acquisition diligence efforts
- Keep track of commercial surgical robots and simulators
- Originator of VIST endovascular simulator – still in production 20 yrs

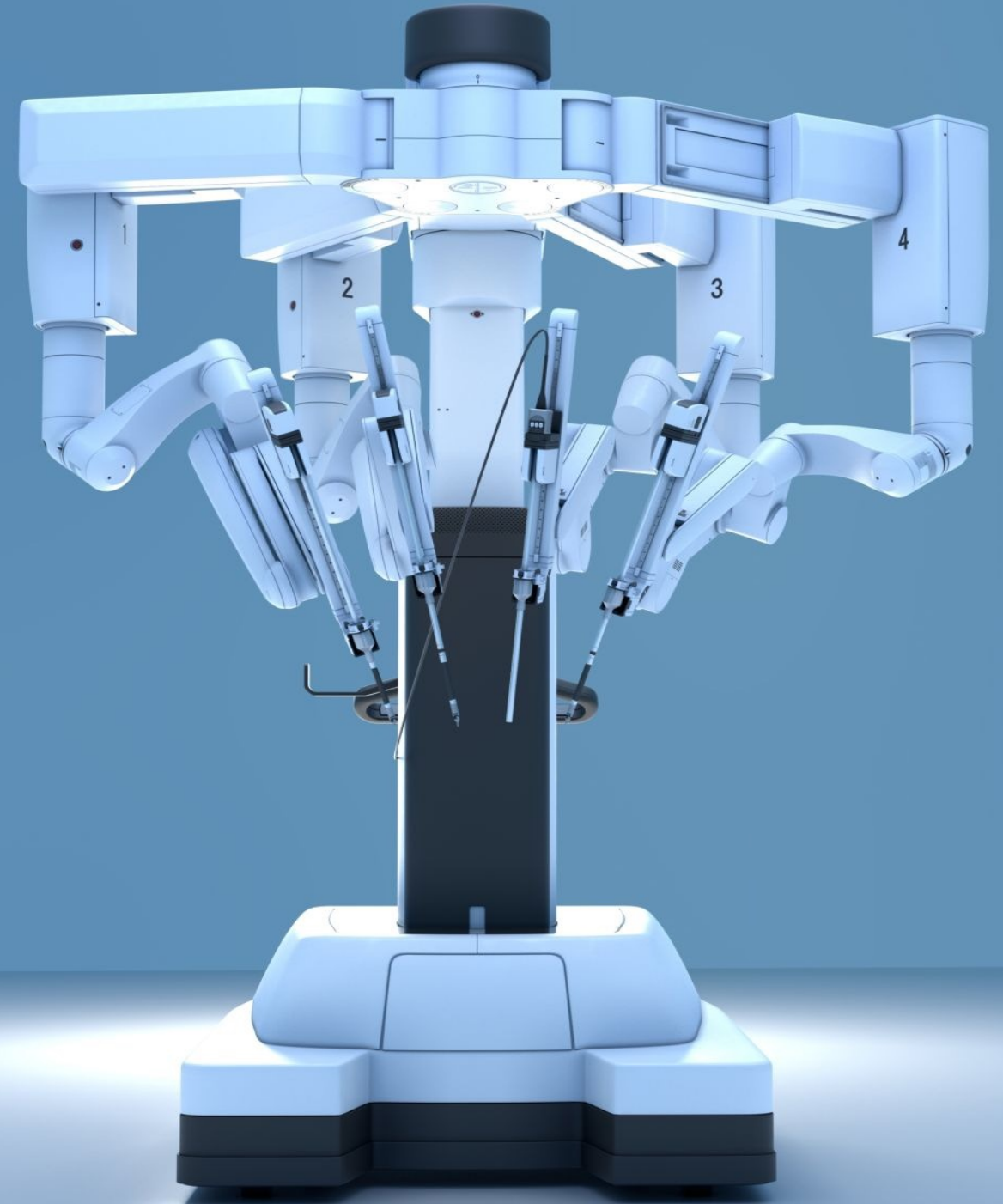
This talk...

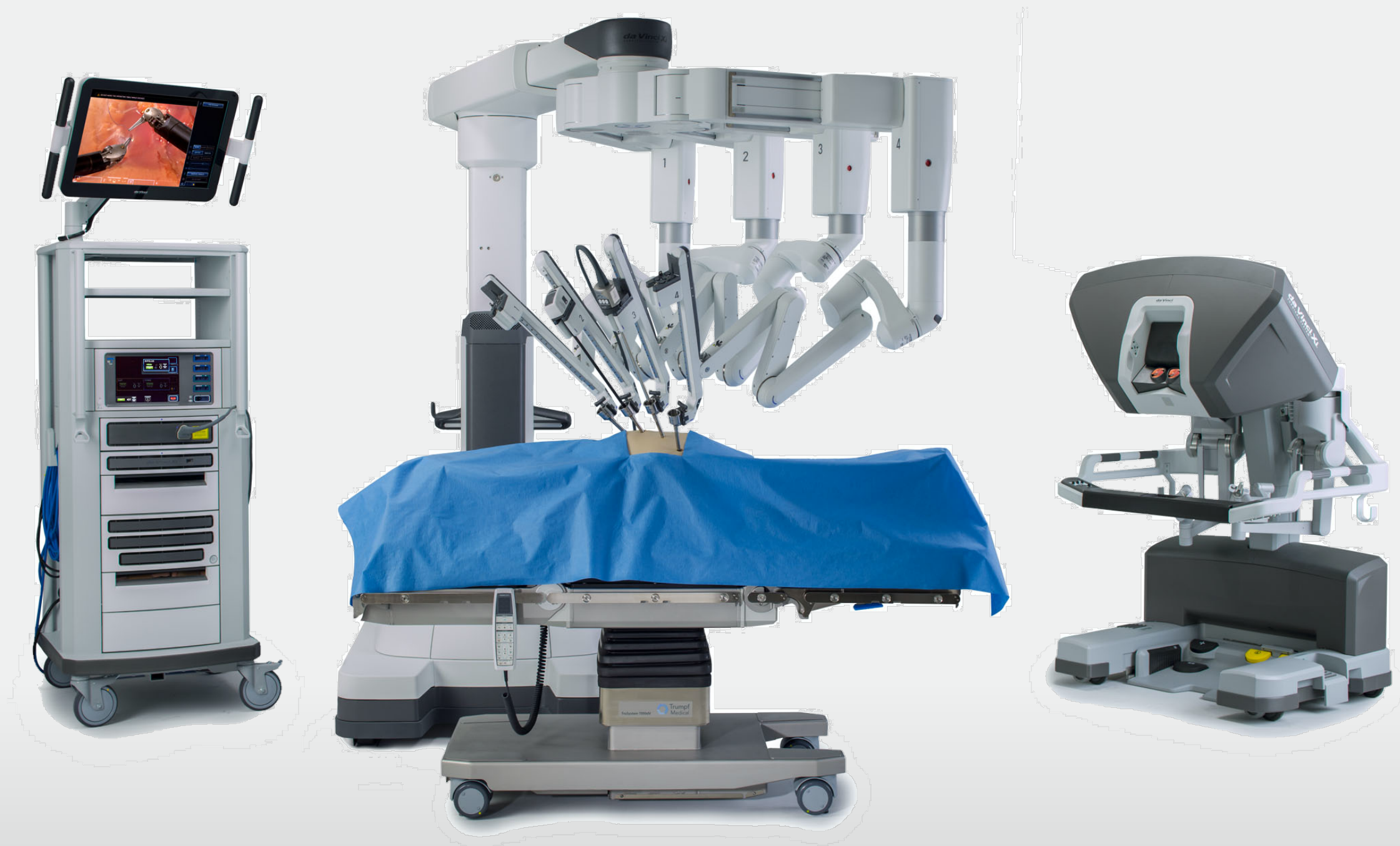
- Is
 - Bits and pieces of my insights from 20 years in surgical robotics
 - Views for the small company on how big companies think
- Is not
 - An MBA in how to start a surgical robotics company
 - See Bill Aulet's book "Disciplined Entrepreneurship"
 - Also Stanford Biodesign Program
 - An exposition on best engineering/product processes/practices
 - See Stanford d.school methodology amongst others
 - By any means exhaustive

Focuses

- Where do things stand in surgical robotics
- A look at surgical robotics acquisitions
- Things to sort out before you start
- Some things to consider in the midst of it all
- Some trends
- Single thought to take away

What is a
surgical robot?





Surgical robotics today

3 | 4 COMPANIES

What are they?

203 under development

27 uncertain

40 on the market

34 acquired

12 dead

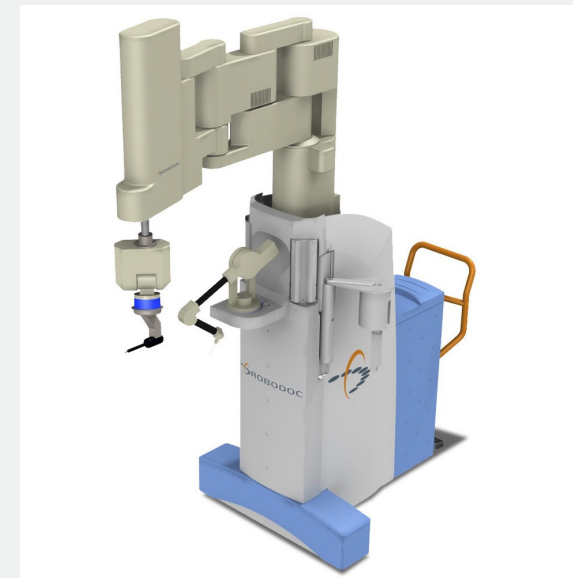
There are more – Stealth & non-US companies

How they work

Autonomous



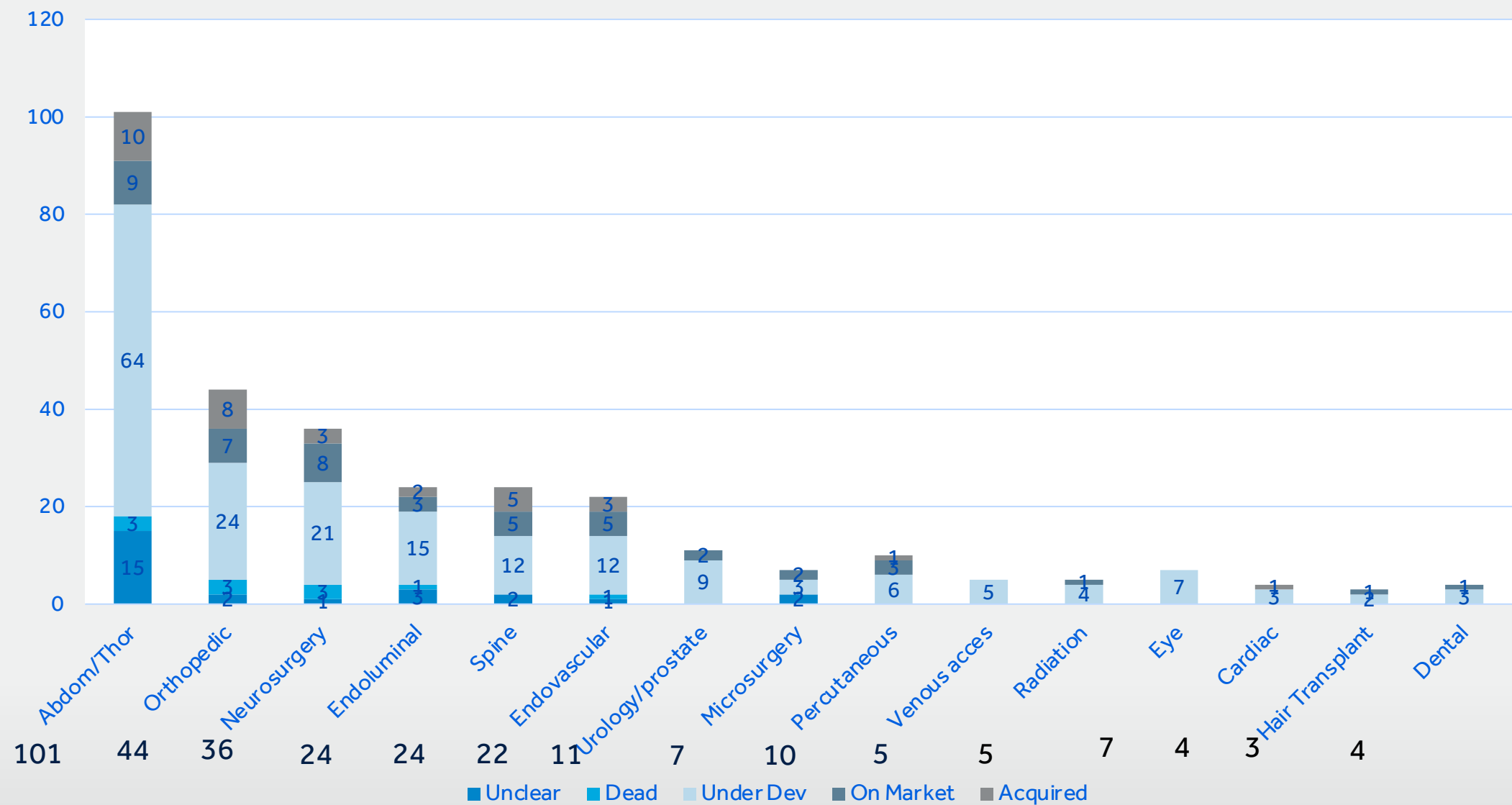
Preplanned



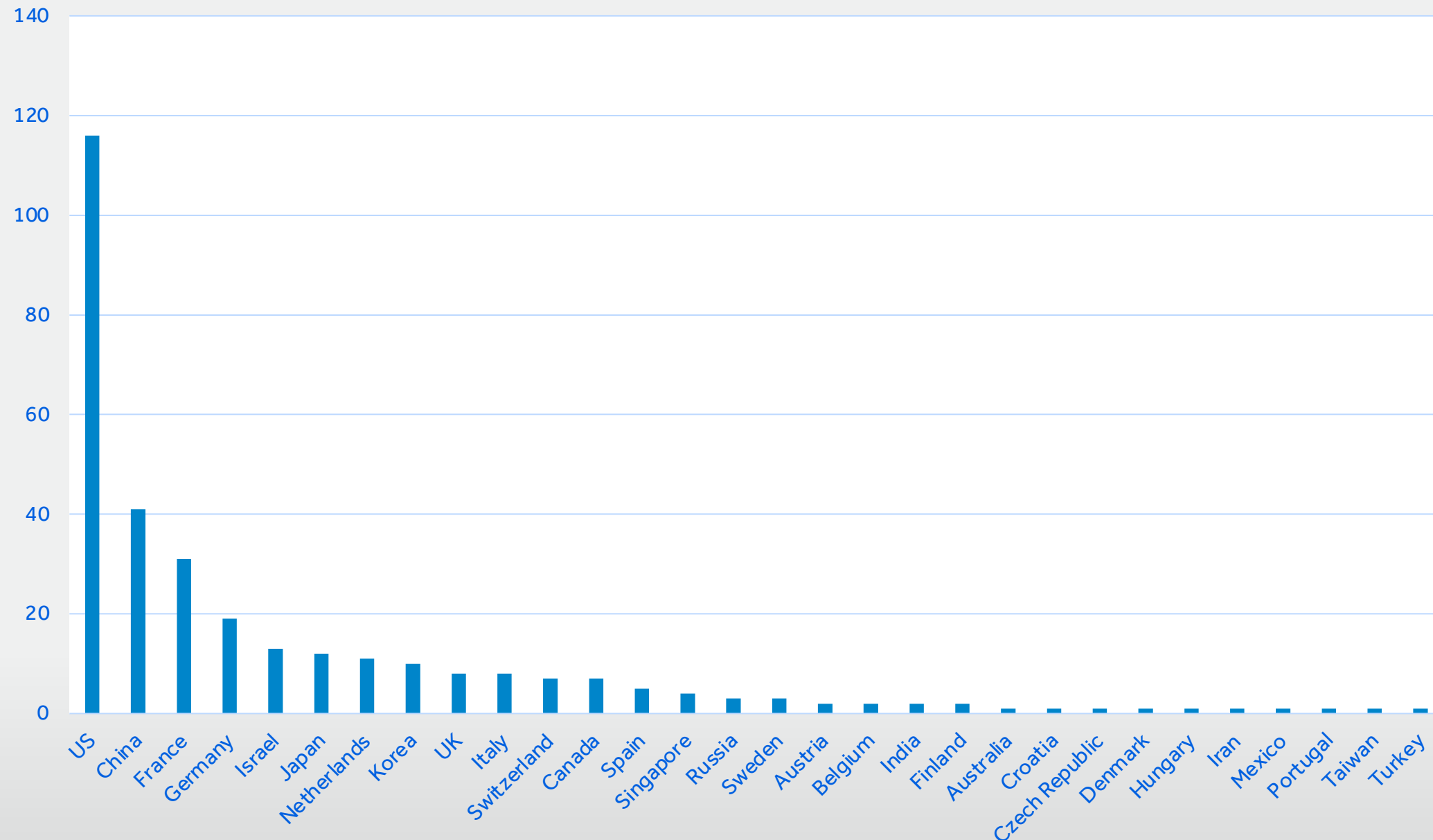
Teleoperation



Focus is predominantly in abdominal procedures

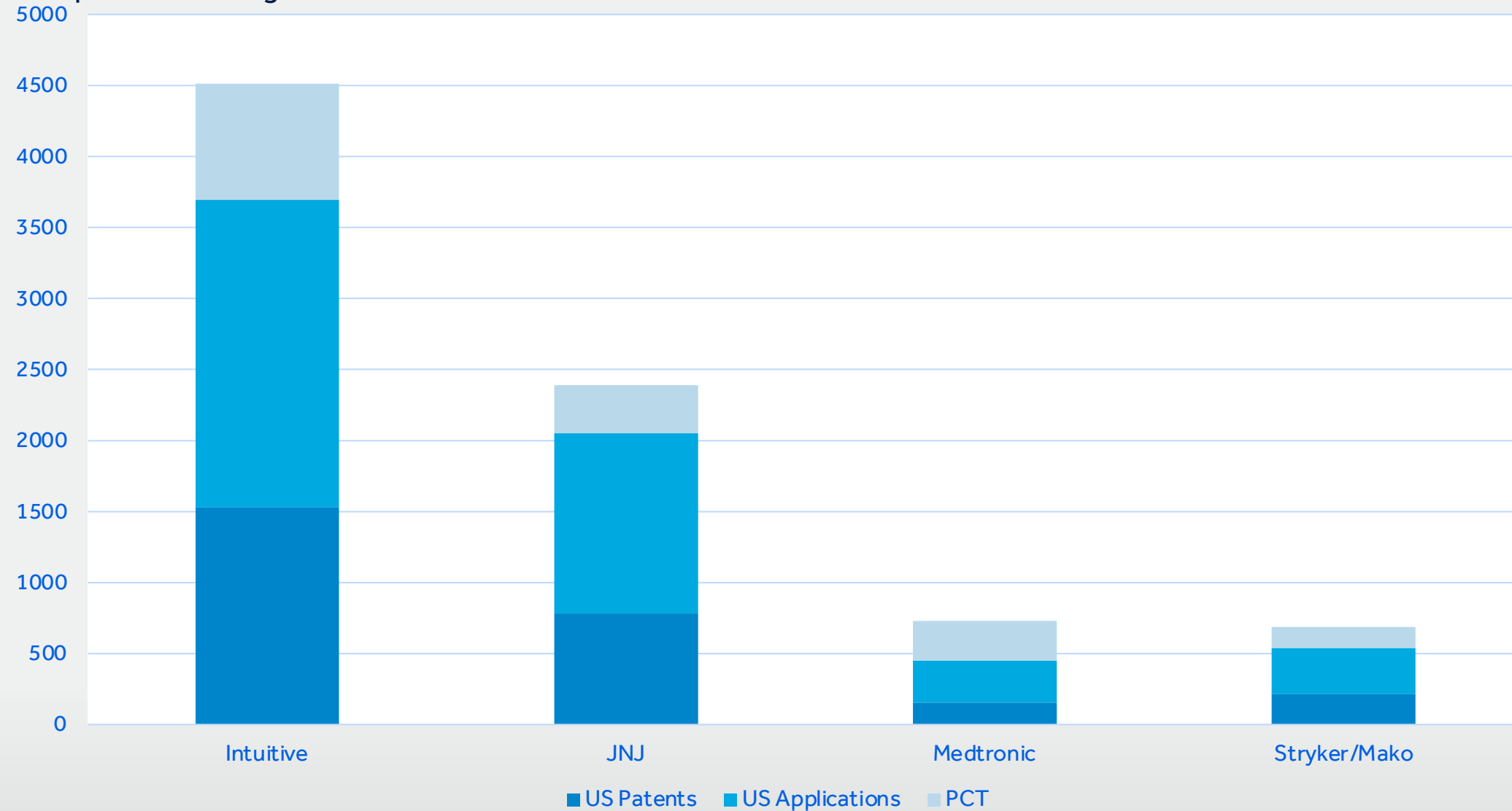


The US has the most surgical robotics startups



While there have been many patents published...

Total patents for largest holders

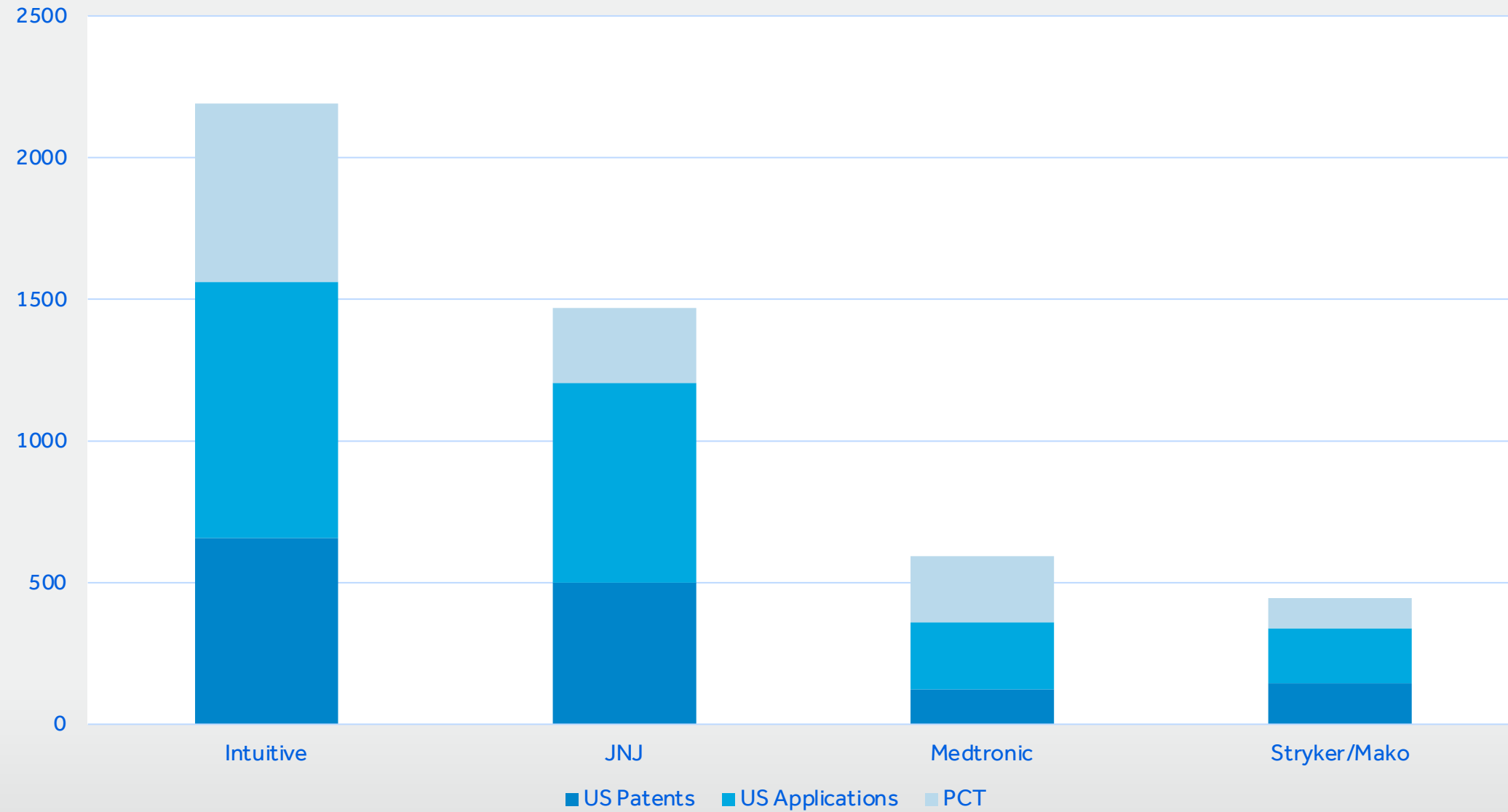


Data from Google Patents

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...many are extensions of existing IP

Patent families for largest holders



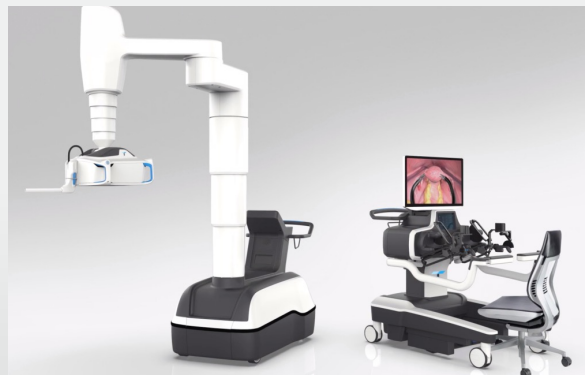
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Abdominal/Thoracic



INTUITIVE
SURGICAL



TITAN MEDICAL™



CMR
SURGICAL



computermotion.



endoVia



Medtronic

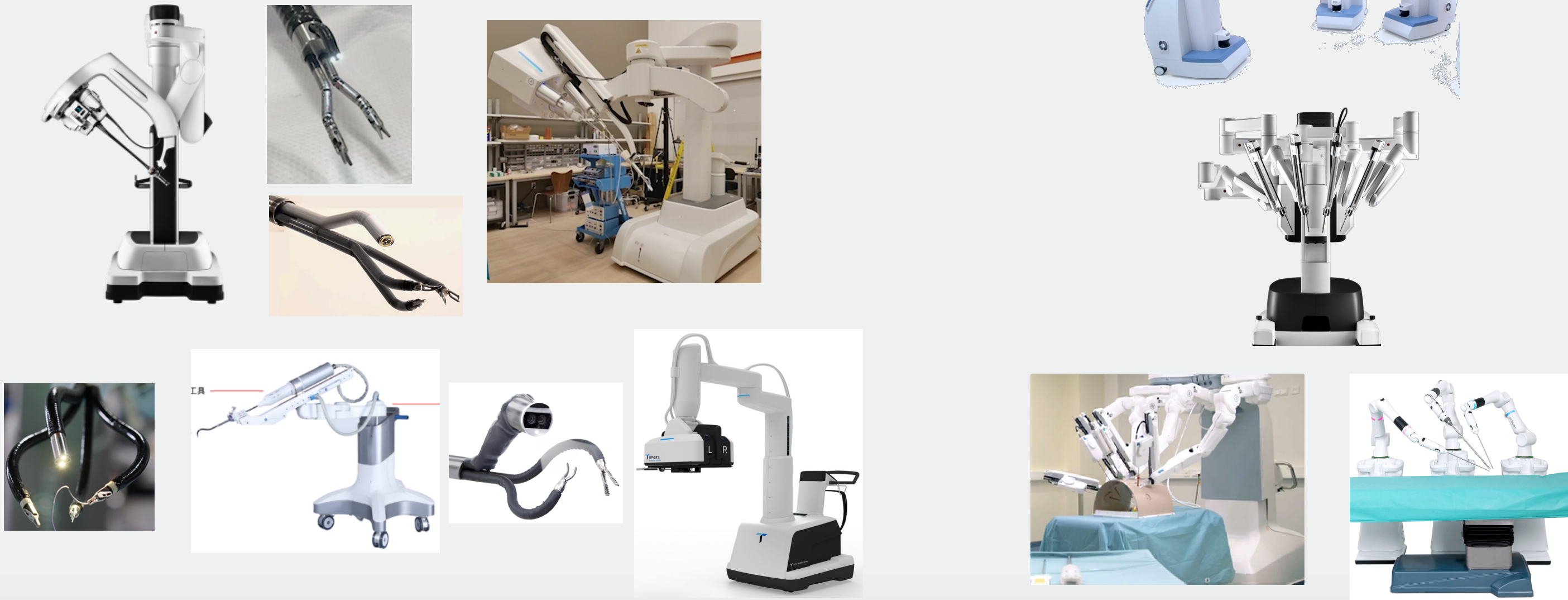


TransEnterix



Representative examples

Abdominal/Thoracic Form Factors



14 Single port

76 Multi port

Representative examples

Orthopedics



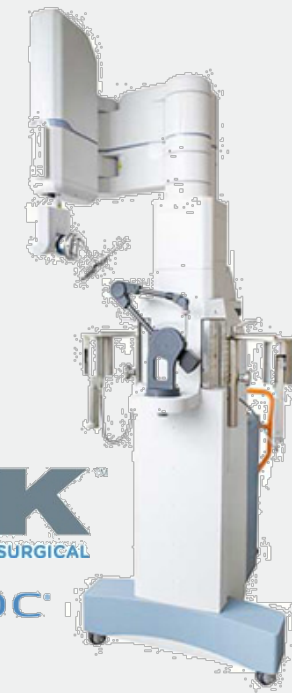
stryker[®]
Orthopaedics

MAKO
SURGICAL CORP.[®]



MAQUET
GETINGE GROUP

THINK
SURGICAL
ROBODOC
Curexo Technology Corporation



stryker[®]
S Stanmore
Implants

acrobot
Precision Surgical Systems



smith&nephew

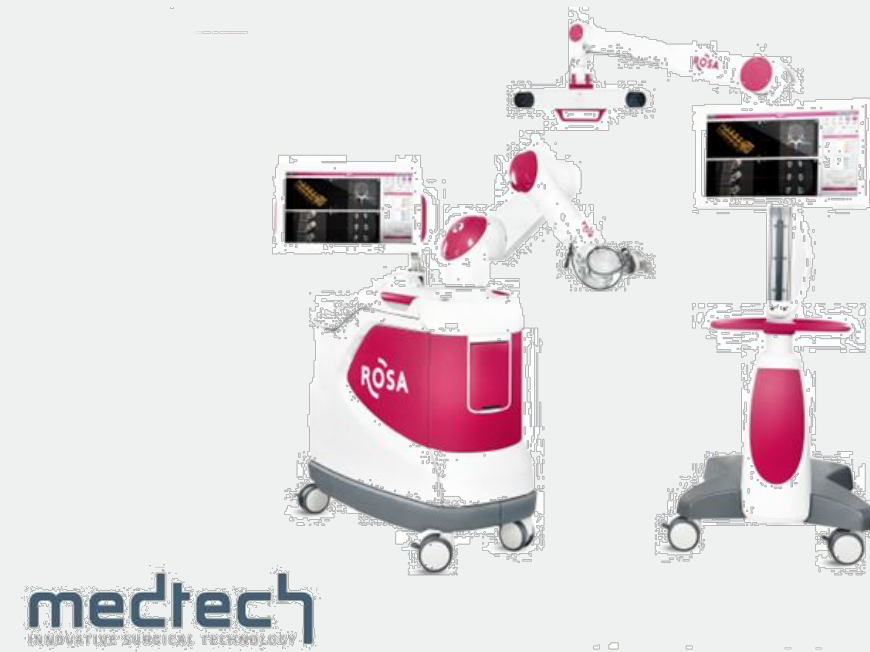
BLUE BELT TECHNOLOGIES, INC.



Representative examples

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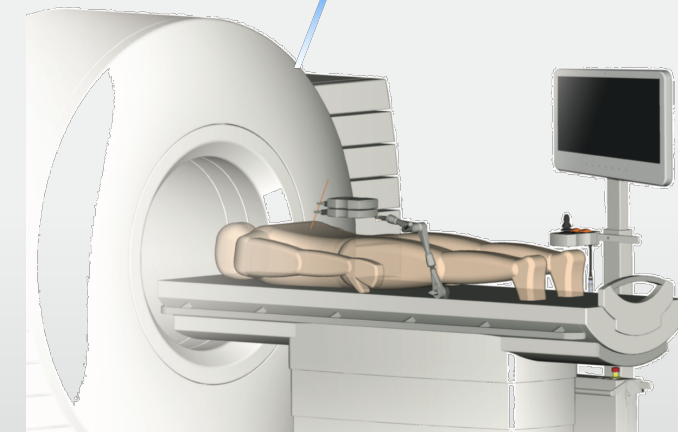
Spinal



KB  MEDICAL



interventional
systems



Representative examples

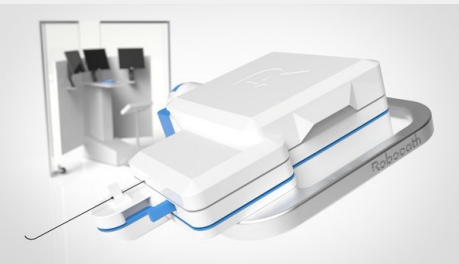
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Endovascular

Catheter Robotics



Corindus
A Siemens Healthineers Company



Robocath



microbot
medical

aeon scientific

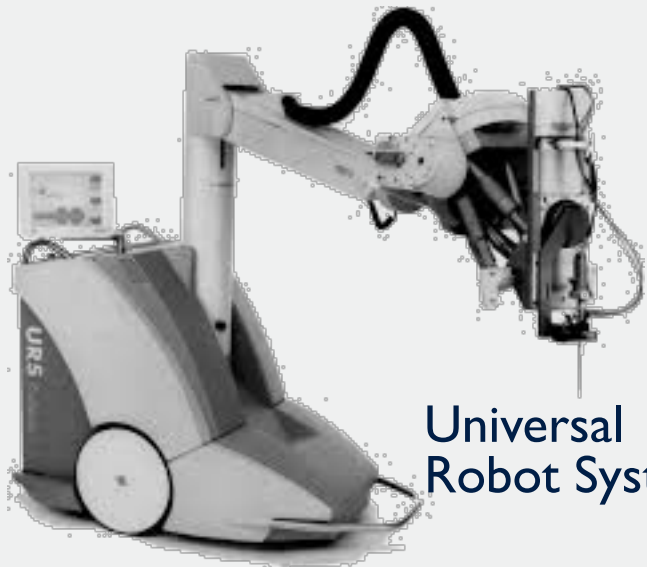


hansen
MEDICAL



Representative examples

Neurosurgery



Universal
Robot Systems



Axilum
Robotics
Assisting you in technical procedures



IMRIS
DEERFIELD IMAGING



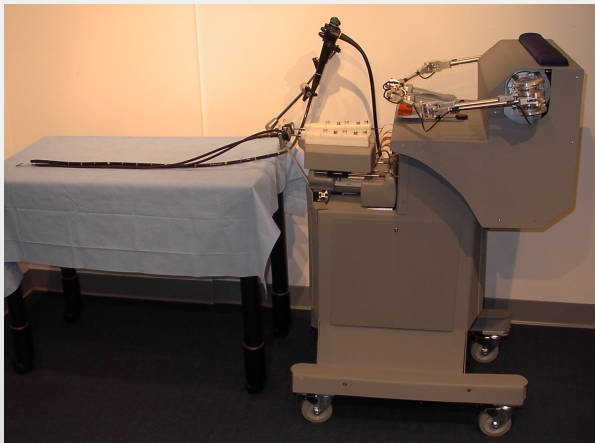
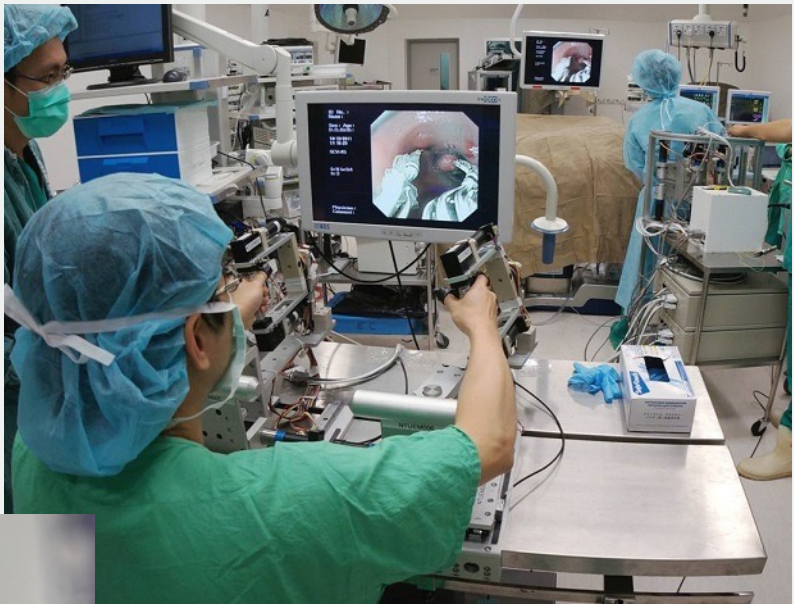
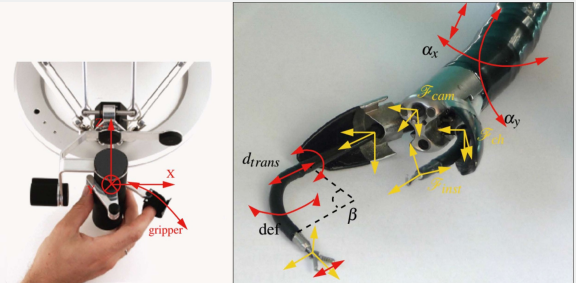
RENISHAW
apply innovation™



ELEKTA

Representative examples

Endoluminal



Representative examples

Urology/Prostate



edap tms
Bringing New Horizons to Therapy

HistoSonics®



**POLYMER
ROBOTICS**



**PROCEPT
BIOBOTICS**

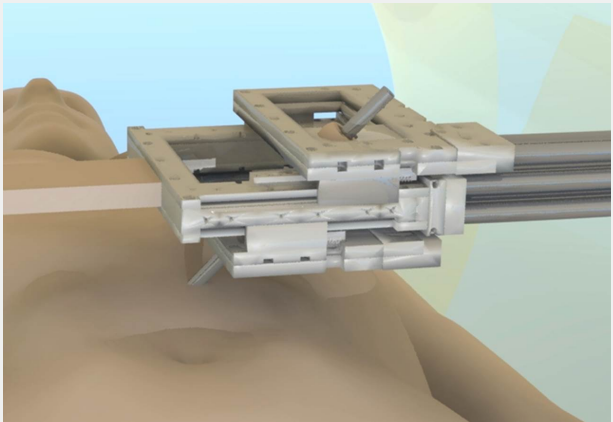
biobot



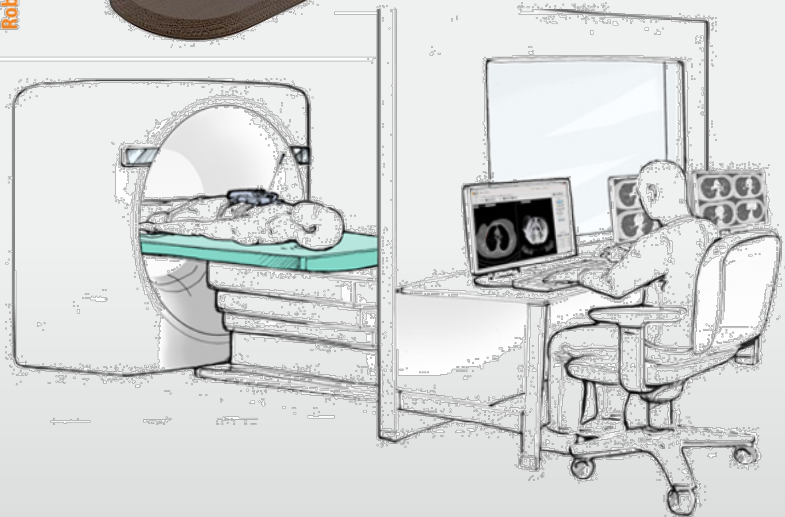
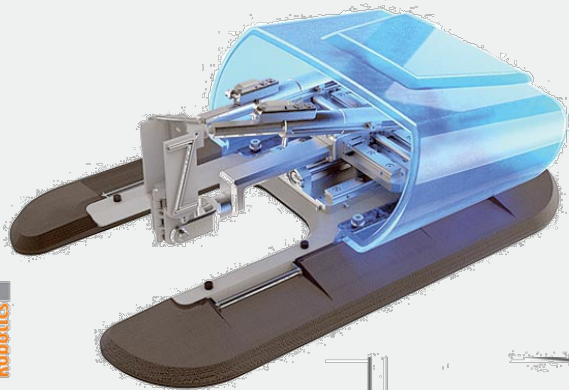
Representative examples

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Percutaneous



GUIDABOT, LLC



Representative examples

Companies whose status changed...

Dead

Boston Scientific (colonoscope)
Electa (neurosurgery scope)
Endobotics (abdominal)
EndoRobotics (endoluminal)
ISIS Robotics (abdominal)
Maquet (orthopedic)
Medrobotics (otolaryngology)
Omniboros (abdominal) – restart as Activ
Sagitta Robotics (orthopedic)
St Jude (Electrophysiology)
Universal Robotics (neurosurgery)

Acquired

Acrobot/Stanmore	Innomedic/Stryker	Stanmore/Stryker
Auris Health/JNJ	KB Medical/Globus	
Blue Belt /Smith&Nephew	Mako Surgical/Stryker	
Cardan Robotics/Stryker	Mazor/Medtronic	
Computer Motion/ISRG	Medineering/BrainLab	
Corindus/Siemens	MST/Transenterix	
Cyberheart/Varian	MedTech/Zimmer	
Devicor/Leica	Microdexterity/Stryker	
Endocontrol/Canady	Neoguide/ISRG	
endoVia Medical/Hansen	Omnilife/Corin	
Endoways/Microbot	Orthotaxy/JNJ	
Excelsius Surgical/Globus	Restoration Robotics/Venus	
Gomtec/ABB	SOFAR/Transenterix	
Hansen/Auris	SRI/Verb/JNJ	

Acquisition
often takes
10+ years

COMPANIES	FOCUS AREA	COUNTRY	INVESTMENT(\$M)	# ROUNDS	ACQ PRICE (\$M)	ACQ YEAR	AGE	# INVESTORS	ACQUIRER
ACROBOT	orthopedic	UK	5	1	UD	2010	~5	3	Stanmore
AURIS HEALTH	abdominal/thoracic	US	733	8	3400	2019	12	13	JNJ
BLUE BELT TECHNOLOGIES	orthopedic	US	45	2	275	2015	12	1?	Smith&Nephew
CARDAN ROBOTICS*	spine	US	45	2	500	2019	11	1	Stryker
COMPUTER MOTION	abdominal/thoracic	US	?	?	55	2003	14	?	Intuitive
CORINDUS	endovascular	US	134	7	1100	2019	18	4	Siemens
CYBERHEART	cardiac	US	24	4	UD	2019	13	3	Varian
ENDOCONTROL	abdominal/thoracic	France	6	1	UD	2019	13	2	Canady Robotics
ENDOVIA MEDICAL	abdominal/thoracic	US	12	4	5	2004	6	3?	Hansen Medical
EXCELSIUS SURGICAL	spine	US	5.5	1	UD	2014	3	?	Globus
HANSEN MEDICAL	endovascular	US	116	5	240(IPO) + 80	2016	13	5	Auris
INNOMEDIC*	orthopedic	Germany	?	?	?	2008	~8	?	Synthes
KB MEDICAL	spine	Switzerland	7	4	UD	2017	5	3	Globus
MAKO SURGICAL	orthopedic	US	95	5	51(IPO) + 1700	2013	5	7	Stryker
MAZOR SURGICAL TECH	spine	Israel	70	3	1700	2018	17	6	Medtronic
MEDICAL SURGERY TECH	abdominal/thoracic	Israel	14	2	UD	2018	13	6	Transenterix
MEDINEERING	neuro	Germany	UD	2	UD	2019	5	4	Brainlab
MEDTECH	neuro & spine	France	2	1	188	2016	14	1	Zimmer
MICRODEXTERITY	orthopedic	US	UD	?	UD	2010	17	?	Stryker
NEOGUIDE	gastroenterology	US	39	2	UD	2009	9	9	Intuitive
OMNILIFE SCIENCE	orthopedic	US	32	3	UD	2019	20	2	Corin Group
ORTHOTAXY	orthopedic	France	?	?	UD	2018	9	?	JNJ
RESTORATION ROBOTICS	hair	US	129	9	25(IPO) + UD	2019	17	5	Venus Concepts
SOFAR	abdominal/thoracic	Italy	?	?	100	2015	~7	1?	Transenterix
STANMORE IMPLANTS*	orthopedic	UK	34	?	42	2016	6 / 68	?	Stryker
VERB SURGICAL	abdominal/thoracic	US	~500	1	UD	2020	5	2	JNJ

*Special aspects
UD - Undisclosed

Special Acquisition Corporations (SPACS)



debut on Wall Street on Monday. The company closed its previously announced business combination with D8 Holdings Corp. last week, gathering \$220 million in gross proceeds. The deal, announced this past April, valued the combined company at an enterprise value of approximately \$1.1 billion.



Israel medical device company **Memic Innovative Surgery Ltd.** today announced the signing of a definitive agreement for a SPAC merger with MedTech Acquisition Corporation (Nasdaq: MTAC). The merged company will have \$360 million cash and an equity value of more than \$1 billion.

Things to sort out before you start

- What makes you unique?
- Be acquired or build a standalone business?
- Is this a standalone technology or an add-on to an existing platform?
- Is there value in the people as well as the product?
Do you hire full-timers or contract out?
- Is there a theme to guide your approach?
MDT – Robotics for the cost of laparoscopy
- Can you do this while still having a day job?
Some people think you should go all in
If idea is not yet in prototype form, think about doing it on the side
This is nicely compatible with SBIRs in the US
Careful with employment/IP assignment agreements, esp. big companies

Money things to sort out before you start

- What are the funds available for the therapy I am delivering?
Can I work within a current reimbursement code?
- Envisioned exit value (presuming acquisition) based on comparables?
Can I do the business for 1/10 - 1/5 of what I expect the exit to be?
- Everyone has to make money and/or benefit from your product
- Do you need who pays for the robot to capture the revenue?
- Can your product support 80-90% margins? (if you are single use)
- If reusable (either software or hardware), how do you make money?
Upfront cost that needs to be paid back quickly from per procedure fees?
- Can you leverage the whole value-based trend?
Almost like an insurance policy approach – indirect payment
- Can I manage to get SBIRs early on to make me more fundable?
No dilution
Forces thinking through what you need to do and what it will become
Use to get through initial idea stage so you have an investor prototype
Study previously successful SBIRs
Consider volunteering as a reviewer

Things to consider in the midst of it all

- Figuring it out
Residents/Fellows get you +80% there for the medical part. KOLs later
Careful to not make a quirky thing for a non-representative surgeon
Watch confirmation bias
 - Document the decision process so you can rewind to the wrong decision, no further
 - Big companies
Have enormous resources to figure out market niches and specific features/functionality details — don't think you can beat that
Figure out how to get one (or more) to help you figure out your product
Care a lot about CoGs and manufacturability
Tough to build to the exact platforms and you do not want to
 - You want your product to be useful across companies/platforms
 - Build a full solution, but plan for it to be broken up to fit into another platform
 - Make sure your surrogate robot is reflective of your acquisition targets' arms
- Interest overwhelms
- 30-50 people on salary want to know all manner of minutiae about you
 - Potentially vast numbers of meetings and it still fails for some dumb reason
- Will find out in diligence if you stretch reality; Investors, not as much

Things to consider in the midst of it all

- Project stuff

Verification – I built what I said I would build

Validation – I built the right thing

Validation matters most early – rapidly evolve the design

Verification is for consistent manufacturing & FDA equivalence

Consider not having dedicated verification engineers – aligned priorities

- Designer
- Test Developer
- Test Performer

Don't overdo specifications

- Careful on precision as well as ranges
- Walking back design history file spec is time consuming and worrisome to FDA

Getting comparables data for specifications is hard

- Large companies can buy and test competitors' products
- Best chance is either a 510k predicate or academic paper
- But e.g., AFAIK there are no public papers characterizing the daVinci Xi or SP
- Unfortunately 510k public versions rarely disclose detail level needed for specs

Just because it is not on the market, does not mean folks have not done it

- It may be more than an engineering issue – benefit, costs, hassle

Things to consider in the midst of it all

- Project stuff

Human factors/UX matters. Get to it early

Plan on at least 5 iterations, even if you do know what you are building

- Pre-iteration – Ill-specified period of subsystem builds
- 1 Proof of concept
- 2 Incorporate learnings from POC bench, animal, & cadaver testing
- 3 Pre-verification and validation build incorporating POC2 test insights
- 4 V&V build used for clinicals
- 5 Final product build

Abstract away from the surgical minutiae. What is really the goal?

Don't restrict yourself to only using robotics on existing hand processes

Don't fear annoying surgeons, but don't be profligate about it

Electrical interfaces into sensorized tools is a major issue for platforms

Things to consider in the midst of it all

- Figuring out your FDA approach

Find your comparables

Seek patterns in the 510k approvals

- common predicates
- common prep/filing/evaluation companies

FDA changed the floor for robots? – requiring clinical data?

Look into Breakthrough designation

- IP

The longer the base claim, the probably less effective the patent

There is almost always a way around things, especially for big companies

Your patents are tools for others with more resources to use some day

Intuitive has had >10 years to prepare for initial broad patents to expire...

- Be thorough, knowledgeable, forthright, friendly – goes a long way

Major trends

- To date

Too many robots in the same specialties and with similar approaches

Too many full platform solutions

The variety of physical and visual control interfaces will be a problem

Just roboticizing what is already done by hand is no longer enough

- Going forward

Opportunity of existing platform enhancement

Lowering the skill bar of operators

- Enhanced surgical site situation awareness
- Contextualization relative to best practices
- Ready availability of mentorship ad-hoc
- Subtask enhancement/automation

Removing the need for technicians to run things

Ability to operate in smaller and/or lower resourced facilities

Lower capital cost

Smaller footprints

Economics tied to outcomes

Move to single use to eliminate reprocessing on site

Higher power density small actuators will change device configurations

Judicious use of soft actuators as well as live hinges

Remember!

Your company is your product

- It's not the thing/service you are developing. It's the whole package
- Capitalization table
Keep it clean. Not zillions of investors. No funky covenants. etc...
- Investment versus acquisition price ratio
Fit with industry priors. Know acquirer expectations
- Competition
Get multiple parties interested in you if at all possible
- Comparables
Be clear and concise as to why specific companies are your comparables
- Where do you fit in the current portfolio?
Tell them how you have designed your product to fit
- Do they want your product or you/your team?
If the team is wanted, there will be tie-ups to make it happen
- Is your IP useful to something that is or will take place?
Can they use it to protect themselves or go after others?
- Your FDA approach is not troublesome (can be annoying...)
All large companies consider their in-house regulatory group to be better
- What are the other big companies doing...
Fitting in the meta trends (e.g. everyone needs a spine robot...)

Putting it into practice

HeartLander Healing the Heart Wall Disruptive Robotic Platform for Ventricular Therapy

Ventricular Procedure Growth

Precise ablations - VT (\$2B, \$540M adr.)

90K ablations in US, 32M WW; \$22K/procedure; \$3K per HeartLander disposable

BiV lead placement - HF (\$28B, \$1.1B adr.)

23M WW with HF, 190K Cardiac Resync Therapy (CRT) procedures in US, 2X for WW; \$75K/procedure

Regenerative therapy - MI (\$300B, \$18B adr.)

790K MIs in US per year, 6M WW; \$50K/procedure

Unaddressed Needs/Challenges

Avoiding open-chest access

Mapping myocardium *in advance*:
costly; sustained VT often impossible

Precise targeting on beating heart wall

Need for elite institution-level skills

HeartLander Solution

Robotic Inchworm Walker

Percutaneous entry

Suction-enabled

Moves over epicardium

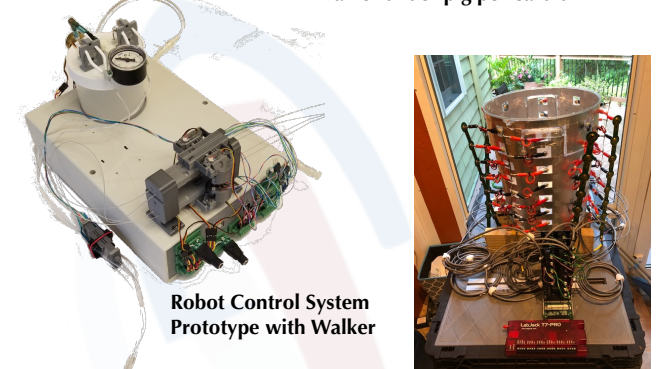
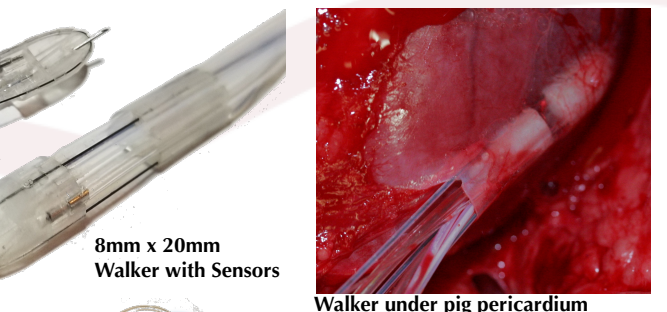
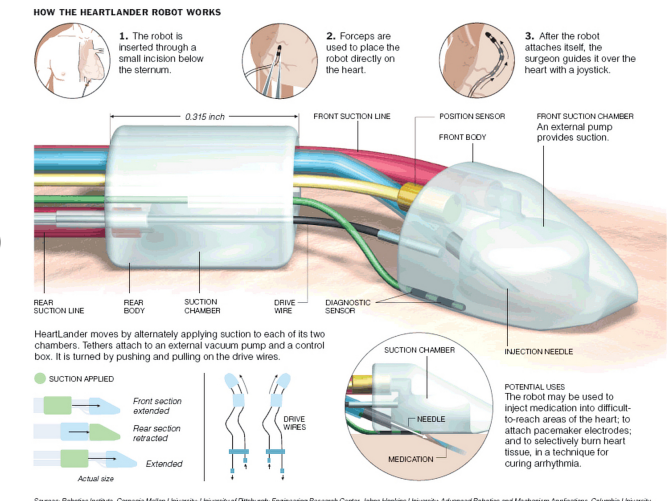
Integrated on-board and external sensing

Myocardial mapping and localization

Navigate manually or via automated control

Precise, needle-based therapy delivery

Minimal capital equipment



Questions?